The Quality Management Plan

Chicago Regional Laboratory Section

U.S. EPA Region 5

United States Environmental Protection Agency
Region 5 Chicago Regional Laboratory
536 South Clark Street
Chicago, IL 60605

List of APPROVERS: U.S. EPA R5

All approvals are done electronically via Qualtrax. To ensure compliance with the EPA and Region 5 QMP requirements, this signature page is provided to list the parties who approved the five (5) year review of this document (QMP version #4). Annual document revision approvals are limited to the laboratory's managers and when needed (as described in section 2.2.2), the Regional and RMD QA Managers. To view the actual electronic signatures via approvals, including names, dates, and time stamps, refer to the "properties" inside the pertinent electronic file. The official CRL Quality Management Plan is located in Qualtrax Documents (module)/Quality Assurance/Quality Management Plan.

The representatives who signed the CRL QMP v4 in 2016 for its 5-year review are listed directly below.

Bruce Sypniewski
Acting Regional Administrator

Kevin Bolger
Regional QA Manager

Tom Brody
RMD QA Manager

Dennis Wesolowski
CRL Laboratory Director

George Schupp
CRL Deputy Director

Angela Ockrassa Davis
CRL QA Coordinator

Table of Contents

1. Acronyms and Definitions

1.1. Acronyms

Acronym	Definition
AB	Accreditation Body
A&I	Analytical and Inorganic
ABN	Acid Base Neutrals
ADOC	Analyst Demonstration of Capability
APLAC	Asia Pacific Laboratory Accreditation Cooperation
BS	Blank Spike, same as LCS
BSD	Blank Spike Duplicate, same as LCSD
CA	Corrective Action
CAR	Corrective Action Report
CBI	Confidential Business Information
CC	Client Contact as it pertains to the database
CCV	Continuing Calibration Verification
CHO	Chemical Hygiene Officer
CID	Criminal Investigation Division
CIT	CRL Improvement Team
CO	Certification Officer
COC	Chain of Custody
CRL	EPA Region 5, Chicago Regional Laboratory
DOC	Demonstration of Capability
DQO	Data Quality Objectives
DW	Drinking Water
EDD	Electronic Data Deliverable
EPA	United States Environmental Protection Agency
EPA QA/G-8	EPA Guidance on Environmental Data Verification and Data Validation
ESAT	Environmental Services Assistance Team contract for Superfund
FOIA	Freedom of Information Act
FTE	Full Time Equivalent
GC	Gas Chromatography
GSA	U.S. General Services Administration
ICP	Inductively Coupled Plasma
ICV	Initial Calibration Verification
IDOC	Initial Demonstration of Capability
IDP	Individual Development Plans for training
ILAC	International Laboratory Accreditation Cooperation
ISO/IEC	International Organization for Standardization / International Electrotechnical Commission
LAN	Local Area Network for linking computers

LCMS	Liquid Chromatography Mass Spectrometry
LIMS	Laboratory Information Management System
MDL	Method Detection Limit
MRA	Mutual Recognition Arrangement
MS	Mass Spectrometry
MSR	Management System Review
NDVR	New Document Version Record
OM	Organic Methods
ORISE	Oak Ridge Institute for Science and Education – source of some CRL interns
P&A	Precision and Accuracy Samples
PA	Preventive Actions
PCH	Purchase Card Holder
PT	Proficiency Testing
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Audit
RL	Method Reporting Limit
RMD	Region 5 Resources Management Division
RPD	Relative Percent Difference
SDS	Safety Data Sheet
SEE	Senior Environmental Employee
SEEP	Senior Environmental Employment Program
SOP	Standard Operating Procedure
SRM	Standard Reference Material
SVOA	Semivolatile Organic Compounds
TOCOR/COR	Task Order Contracting Officer Representative/ Contracting Officer Representative
TSA	Technical System Audit
VOA	Volatile Organic Analysis
WI	Work Instruction
WO	Work Order

1.2. Definitions

- Batch – A group of samples prepared or analyzed at the same time using the same equipment, methods and reagents.

- Calibration Blank – A volume of reagent water fortified with the same matrix as the calibration standards, but without the analytes. Internal standards or surrogate analytes may or may not be present.

- Calibration Standard – A solution prepared from a primary standard solution or stock standard solutions, with any applicable internal standards and surrogate analytes. The calibration standard solutions are used to calibrate the instrument response with respect to known analyte concentrations.

- Continuing Calibration Blank – A calibration blank analyzed in the course of the analysis run to demonstrate that the instrument continues to be capable of acceptable performance. Control limits are documented in the analytical SOP.

- Continuing Calibration Verification, Continuing Verification Standard – A control standard analyzed in the course of the analysis run to demonstrate that the initial calibration remains valid through the course of the analytical run. It has acceptance limits defined in the SOP.

- Control Standard – Control standards are prepared in the same manner as the calibration standard. The control solutions are used to demonstrate that the instrument is capable of acceptable performance with control limits stated in the SOP.

- Data Package – The paper file of information that the laboratory generates about a work order.

- Data Review – An in-house examination of data to ensure that data have been recorded, transmitted and processed correctly including checks for errors in transcription, calculation, reduction and transformation as well as completeness of sampling information or losses of samples or data.

- Data Verification – A process of evaluating completeness, correctness and conformance/compliance of a specific data set against the method, procedural or contractual requirements. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

- Field Duplicate – Two separate samples collected at the same time and placed under identical circumstances and treated exactly the same through the field and laboratory procedures. Analyses of a number of field duplicate pairs will indicate the precision associated with sample collection, preservation and storage, as well as laboratory procedures.

- "G" Drive – One of CRL's shared drives with full rights granted to all staff members. The G drive is backed up by IMB periodically during the week. The network address of the stated share drive is \\204.46.201.26\Root Share\R5CHEM\Vol1\User.

- Group – Several associated CRL chemists that do similar analyses. Usually members of a group are qualified as backup analysts for others in the group.

- "I" Drive – One of CRL's secure shared drives which houses documents related to CRL's analytical data. Limited rights are given to all staff members except group leaders, the CRL QA Coordinator, and the CRL Deputy Director. The limited rights on this share drive prevent staff from altering, adding, deleting or overwriting files. Group leaders have rights to create and delete folders. Full rights are granted to the CRL QA Coordinator and CRL Deputy Director. The network address of the stated share drive is \\204.46.201.26\Root Share\R5CRL.

- Initial Calibration Blank – A calibration blank analyzed at the beginning of the analysis run to demonstrate that the instrument is capable of acceptable performance.

- Initial Calibration Verification – A control standard, generally from a different source or lot than the Calibration Standard, generally from a different source or lot than the Calibration Standard, analyzed at the beginning of the analysis run to demonstrate that the instrument is capable of acceptable performance. It has limits documented in the SOP that may come from a published method.

- Instrument Performance Check Solution – A solution of one or more method analytes, surrogates, internal standards or other test substances used to evaluate the performance of the instrument system with respect to a defined set of criteria.

- Intern – An educationally qualified person that assists with analyses or special projects in the CRL for a specified period of time to gain experience. An interns is usually not EPA employee. Generally, they are paid for their time and may write papers concerning their work.

- Laboratory Blank – Also known as "Method Blank." An aliquot of reagent water or other blank matrix treated exactly like a sample, including exposure to all glassware, equipment, solvents, reagents, internal standards and surrogates that are used with other samples. The laboratory blank is used to determine if method analytes or other interferences are present in the laboratory environment, reagents or apparatus.

- Laboratory Control Samples – An aliquot of reagent water or other blank matrices to which known quantities of method analytes are added in the laboratory. The LCS is analyzed exactly like a sample with all preparation steps. The purpose is to determine whether the methodology is in control, and whether the laboratory is capable of making accurate and precise measurements.

- Laboratory Duplicate – Two aliquots of the same sample taken in the laboratory and analyzed separately with identical procedures. Statistical limits for the Relative Percent Difference are calculated from historical data and included in the SOP. In this laboratory, if the absolute value of the difference is less than or equal to the method detection limit, the duplicates are valid and pass. The limits indicate the precision associated with laboratory procedures, but not with sample collection, preservation or storage procedures.

- LIMS – A computer database where sample results and all relevant data are stored. Currently the laboratory uses the Element LIMS system by Promium.

- Linear Calibration Range, Linear Range – The concentration ranges where the instrument response is linear or approximates linearity.

- Matrix Spike – An aliquot of an environmental sample to which known quantities of method analytes are added in the laboratory. The MS is analyzed exactly like a sample with all preparation steps that the parent sample received. The purpose is to determine whether the sample matrix contributes bias to the analytical results. Background concentrations of the analytes in the sample matrix must be determined in the parent sample and used to correct the measured values in the MS. Recoveries will have statistical limits listed in the SOP.

- Matrix Spike Duplicate – Another aliquot of the same parent sample treated in the same manner as a Matrix Spike. Matrix duplicate differences may have limits listed in the SOP.

- Method Detection Limit – The minimum concentrations of analyte that can be identified measured and reported with 99% confidence that the analyte concentration is greater than zero.

- One Drive/Note – The One Drive and One Note are collaborative tools that stem from Office 365 and are frequently used in EPA's Microsoft environment.

- Original Observation – All observations made concerning sample analysis with enough detail to reconstruct individual and specific analysis from beginning to end. Original observations must be documented. Examples include, but not limited to, various types of documentations such as hard copies of instrument print-outs, bench sheets, data logbook entries, and other forms of supporting data.

- Pen & Ink – A common term used to define a procedure for documenting a one-time or continuous deviation (policy or procedure) in a Quality Assurance (QA) document.

- Policy - Actions adopted by CRL in order to produce data with known quality, follow good laboratory practice and to meet the laboratory's accreditation standards. CRL policies are required actions that are many times are associated with procedures documented in this QMP, SOPs, WIs, or forms. CRL's policies do not supersede any Agency, Regional or Divisional policies currently in effect.

- Proficiency Testing Sample – A sample intended to challenge the laboratory's analytical processes, generally from a commercial provider. The sample may contain more than one vial and have multiple levels of analysis for one method.

- Quality Control Samples – Samples that monitor the performance of the instrument, method and preparation.

- Qualtrax – A compliance management software used by CRL to control and manage quality documents electronically as well as meet laboratory accreditation standards.

- Reagents – A substance that is used in analysis due to its reaction. Test strips and polyseeds are considered reagents.

- Recertify – Typically for supporting equipment, recertification includes a process which involves verifying the performance accuracy of a machine at a given point in time. This information is normally captured under the "before" or "as found" data in vendor certificates. At times, and specifically for some supporting equipment such as pipettes, recalibration is needed. Recalibration involves making adjustments to an instrument or supporting equipment and doing whatever is necessary to restore the machine to its original performance accuracy parameters. This information is usually represented under the "after" or "as left" data in the vendor certificates. CRL uses the term "recertify" to capture this entire process, even when recalibration applies.

- Reporting Limit – This is the lowest concentration reported by CRL except in the case of a special request.

- Reporting Limit Verification - A standard used to demonstrate analyte recovery at the RL listed in the SOP.

- Revision – At CRL the term 'revision' refers to a review, and edit where appropriate, of the entire document. Example; standard scheduled annual document revisions. Regardless of whether a document undergoes a complete or partial review and edits, the version number changes to the next whole number.

- Safety Data Sheet – Written information provided by vendors concerning a chemical's toxicity, health hazards, physical properties, fire and reactivity data including storage, spill and handling precautions.

- SharePoint site – A web-based, collaborative platform that integrates with Microsoft Office. CRL's SharePoint site is used primarily for client service (e.g. data packages, forms, other info.).

- Stock Standard Solution – A concentrated solution containing one or more method analytes prepared in the laboratory using assayed reference materials or purchased from a reputable commercial source.

- Standard Operating Procedure - Procedural documents that prescribe an approved method through detailed instructions which are to be followed for established quality performance.

- Standard Practice – Recommended (optional) actions intended to support the quality system.

- Validation – Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs

- Version – The term 'version' denotes another document of the same content with changes made (differing in certain respects from its earlier content) which does not necessarily undergo review and edit to the entire document, rather specific sections. Regardless of whether a document undergoes a complete or partial review and edits, the version number changes to the next whole number.

- Work Instruction – Instructions on how to perform a specific task. Normally this task is a detailed part of a procedure such as completing a demonstration of capability study or submitting a pen and ink form, etc.

- Work Order – A group of samples arriving at the laboratory on the same day from the same sampling location. Several work orders from the same sampling location may arrive on sequential days. These work orders may be grouped into a Sample Delivery Group.

- Workflow – A (automatic) procedure that documents steps taken, which require input or output information, to complete an intended process. Workflows are created by a CRL administrator and generated through Qualtrax.

2. Introduction

2.1. Scope and Purpose

2.1.1. Scope

The Region 5 (R5) Chicago Regional Laboratory (CRL) is part of the United States Environmental Protection Agency (EPA). Within EPA, CRL is a branch of the Resources Management Division (RMD). The Region 5 and RMD Quality Management Plans (QMPs) document how the Region's and RMD's quality systems are implemented. The scope of this QMP covers all operations only within the CRL.

The CRL QMP documents how the laboratory's quality system implements a quality management framework. This framework assures CRL-generated data are of known and acceptable quality which are necessary to meet our client's intended uses. The CRL QMP outlines how CRL plans, implements, and assesses the effectiveness of quality assurance and quality control actions in the functioning of its analytical services.

The CRL holds an accreditation to the International Organization for Standardization / International Electrotechnical Commission (ISO/IEC) 17025:2005, commonly referred to in this document as ISO 17025. This accreditation is granted by a third party who attests to the technical competence of CRL following ISO 17025 standards and this Quality Management Plan (QMP) specific to the scope of accreditation. The current accreditation body (AB) for the CRL is Laboratory Accreditation Bureau (L-A-B) which has recently been folded into ANSI-ASQ National Accreditation Board (ANAB). The revised AB name, ANAB, will be effective once the accreditation certificate and scope of accreditation is updated to reflect this change. The laboratory's Standard Operating Procedures (SOPs) not covered under its scope of accreditation are exempt from some ISO 17025 requirements as noted throughout this document. In addition, CRL meets all requirements for the Forensic Science Accreditation Program (FSAP) based on International Laboratory Accreditation Corporation (ILAC) G-19:2002 guidelines. CRL's accreditation certificate and scope is available on the EPA intranet. EPA intranet address: located at http://www.r5intra.epa.gov/div/rmd/CRL/Index.htm

2.1.2. Purpose

This QMP is written to comply with USEPA CIO Policy 2105.0 *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* (May 2000, Reissued January 2008), USEPA CIO Procedure 2105-P-01-0 *EPA Quality Manual for Environmental Programs* (May 2000, Reissued January 2008), EPA QA R-2 EPA *Requirements for Quality Management Plans* (March 2001, Reissued May 2006), ILAC G-19:2002 guidelines and ISO/IEC 17025:2005 standards.

The CRL Director's signature placed on this document represents a concurrence with the content, especially policies contained within and commitment to implement all of the stated directives and requirements. In addition, this signature also represents the signee's agreement to issue the quality policy statement documented in section 3.2.2 and implementation of the quality practices held at CRL.

This QMP documents the laboratory's quality system appropriate to its scope of activity through its policies and standard practices which generate procedures and sometimes outputs. These policies assure quality to the laboratory's system and it also fulfills the laboratory's mission and supports the agency's mission. For CRL's mission statement which includes how it supports the agency mission, refer to section 3.2.3. CRL policies are required actions that are, many times, supported by procedures documented in this QMP, Standard Operating Procedures (SOPs), Work Instructions (WIs), or forms. CRL's policies do not supersede any Agency, Regional or Divisional policies currently in effect. Standard practices are recommended (optional) actions intended to support the quality system. Both policies and standard practices often rely on SOPs and/or WIs to document the established procedure. For more details concerning policies, procedures, and other documents related to CRL's Quality Assurance (QA) system, refer to section 2.3.

2.2. The QMP and QAARWP Review

Policy 001: The CRL shall have a QMP that is regularly reviewed.

2.2.1. QMP Five (5) Year Review and Revision

Policy 001-01: The CRL QMP shall be reviewed for approval by the CRL QA Coordinator, CRL Director, CRL Deputy Director, RMD QA Manager (QAM), Region 5 QA Manager (RQAM), and the Assistant Regional Administrator (ARA) for RMD once every five (5) years.

The CRL QMP is valid for 5 years from the date of last approval. Once approved, the CRL QMP becomes an appendix to the RMD QMP. The last official 5-year cycle review for the CRL QMP (v4) was approved on 07/20/2016.

Per EPA QA/R-2 *EPA Requirements for Quality Management Plans* section 2.7, conditions requiring the revision of an approved QMP include:

- expiration of the five-year life span of the QMP;
- major changes in mission and responsibilities, such as changes in delegation status of a program;
- reorganization of existing functions that effect programs covered by the QMP;
- And assessment findings requiring corrective actions and response as it applies to the bullet items directly above.

An EPA QMP Review Checklist (http://www.epa.gov/quality) is completed by the CRL QA Coordinator and submitted to the RMD QAM and RQAM along with the draft QMP document. A summary of the changes made to this QMP is located in Appendix D, Revision History.

2.2.2. QMP Annual Review and Revision

Policy 001-02: Per CIO 2105-P-01-0 Section 3.2.4, each organization with an approved QMP shall annually review their QMP and determine the need for any revisions.

In consultation with the RMD QAM and RQAM who approved the CRL QMP, the CRL QA Coordinator will determine whether the scope of the CRL QMP revision requires review and approval by the RMD QAM and RQAM.

At CRL, QMP annual revisions may be based on changes in organization, policies or processes. Changes to the QMP may also result from corrective actions based on findings or recommendations from various audits, such as Management System Reviews (MSRs), Quality System Audits (QSAs), or SOP technical audit, as well as appropriate staff suggestions for quality management system improvements and new or modified policy changes approved throughout the year (via CRL Form002).

Annual QMP revisions are also used by CRL management to evaluate the effectiveness of the laboratory quality management system as well as to document the continuous improvements made on a continual basis.

2.2.3. QMP Review and Approval Procedure

The CRL QA Coordinator is responsible for reviewing the QMP and revising it. Modifications made to the QMP are summarized as an appendix to this document called "Revision History." The CRL QMP is a controlled document and is reviewed similar to SOPs and Work Instructions (WIs). All approvals are done electronically via Qualtrax. To ensure compliance with the EPA and Region 5 QMP requirements, this signature page is provided to list the parties who will be approving the five (5) year review of this document. To view the actual electronic signatures via approvals, including names, dates, and time stamps, refer to the "properties" inside the pertinent electronic file. The official CRL Quality Management Plan is located in Qualtrax Documents (module)/Quality Assurance/Quality Management Plan.

2.2.4. Interim Modifications to the QMP

When quality documents need to be modified immediately, refer to section 6.3.4.

2.2.5. QAARWP Annual Review and Report

Policy 001-03: Per EPA QA/R-2, each organization with an approved QMP shall annually report on the status of implementation of their quality system.

Region 5 organizations meet this requirement by reporting their contributed portion of the Region 5 Quality Assurance Annual Report and Work Plan (QAARWP). To comply, CRL must submit their QAARWP items to the RMD QAM for incorporation into RMD's portion of the annual report. The RMD QAM in turn, submits RMD's report to the RQAM.

2.3. Quality Management System

2.3.1. QA System description

The QMP addresses the CRL standards and requirements, to which it must comply with. At CRL, policies are carried out by the use of procedural or output documents. Procedural documents include but are not limited to SOPs and WIs which are discussed in section 2.3.6. Outputs document how procedures were in fact carried out. Outputs such as workflows, forms, spreadsheets, and checklists are in fact a product of procedures and are discussed in section 2.3.7. All types of procedural and output documentations are available in Qualtrax.

2.3.2. QA system lineage

Following is the direction in which the QA managers report to one another in order of agency sectors. EPA section (CRL) → division (RMD) → regional (R5) → national (USEPA Office of Environmental Information (OEI), Director, Quality Staff).

2.3.3. QMP components

The CRL quality system components addressed throughout this document include:

- Quality Management Plan
- Quality Assurance Project Plans (QAPP)
- Data Quality Objective (DQO)
- Workload Scheduling
- Standard Operating Procedure (SOP)
- Management System Review/Quality System Audit (MSR/QSA)
- Corrective Action (CA) Report (CAR)
- Nonconformance Report (NCR)
- Data Verification
- Technical Assessment
- Data Quality Assessment

2.3.4. Qualtrax

Qualtrax is a web-based quality management software used by CRL to centralize, control and manage QA documents, procedures, and trainings electronically. For information concerning paperless QA documents refer to section 6.4.2, Quality documents. Qualtrax, Inc. holds an ISO 9001:2008 accreditation which assists the laboratory when complying to ISO 17025 accreditation standards, as well as eases transition due to various procedural or systematic change (new/modified agency or section requirement), and enhances policy and procedural consistency.

Access to Qualtrax software is granted by user licenses. CRL has two (2) dedicated licenses and five (5) concurrent licenses. Dedicated licenses allow a user to log into Qualtrax at any given time, regardless of how many are logged into the system. Currently, dedicated licenses are granted to the CRL QA Coordinator who also configures CRL's Qualtrax and the Deputy Director who assists in the system configuration. Concurrent licenses allow up to five users to be logged into the system at once and are automatically granted to the first five users logging in, excluding those logged in using dedicated licenses. When all 5 concurrent licenses are occupied, there will not be access into the system until one of the current users logs out.

The CRL Qualtrax system is currently only accessible to agency staff members at http://r0505aclth001/ . EPA agency employees all have viewing rights to this website. Only system users have additional website rights which are determined by the system administrators at CRL. All of the CRL staff members and a few other Region 5 EPA employees (IMB and approving officials) have user accounts and can access the system by entering the user's unique LAN ID and password at the previously stated website. EPA staff members can access this website within Region 5's offices and remotely through the Virtual Private Network (VPN) or Workplace Proxy.

The Qualtrax system has various permissions, which are granted by the system administrator(s) to a group(s) and not individuals. This allows for ease of transition during personnel changes. When the Qualtrax system administrator(s) assigns group permissions, security and traceability should always be considered for the purpose. The primary system administrator is the CRL QA Coordinator.

Users can find operational instructions for the system's workflows, various documents (such as SOPs), and training modules by following the appropriate CRL work instructions as referenced throughout this document. Alternatively, Qualtrax has a "Search" function to assist both system administrators and users.

Following is a list of Qualtrax features.

- Unique IDs
  - All generated products (documents, workflows, tests, etc.) are assigned an individual and unique number.
- Document management
  - Document life cycles are managed automatically.
  - Document revisions are tracked and recorded.
- Workflow management
  - Documents all steps in a procedure including personnel assigned and action approvers (as applicable).
  - Tracks action dates for deadlines and completions with a time stamps.
- Training records management
  - Maintains the laboratory's training records.
- Tests production
  - Produces tests that can be used to document training.

2.3.5. Policies

The policies and procedures described in this QMP are actions adopted by CRL in order to produce data with known quality, follow good laboratory practice and to meet the laboratory's accreditation standards. CRL's policies do not supersede any Agency, Regional or Divisional policies currently in effect. Standard practices are recommended, but as optional actions intended to support the quality system. For a comprehensive list of the current policies and standard practices found in this document, refer to Appendix C. The Policy and Standard Practice List document is also located in Qualtrax Documents under Quality Assurance/References/CRL and QMP.

Policy 002: Lab-wide policies and/or procedures included in new or modified QA documents shall be effective once they are published in Qualtrax upon last approval. Should a policy or procedure need an implementation period, a specific effective date based on this consideration will be documented within the associated QA document.

Once a document is published in Qualtrax, all appropriate users are notified via email (by Qualtrax) and active users provided a New Document Version Record (NDVR) test. For details concerning NDVRs, refer to policy 012-03 under section 6.3.4.

A grandfather clause applies to existing work that would be affected by modified/new internal policies. This is a provision in which an old rule continues to apply to some existing situations in order to complete that work while a new rule will apply to all future cases. Work in progress will still be allowed to proceed without impact of the modified/new policy.

Qualtrax releases a Policy Implementation List (PIL) edited by the CRL QA Coordinator which includes the revision history table of the QMP and other SOPs, such as GEN006, that contain policy changes for a calendar year. Work Instruction revision histories are not included in the PIL since those documents should be referenced continually as needed.

Policy 002-01: QMP exemptions or planned, one-time deviations must be documented.

QMP exceptions and/or planned deviations may be documented in one of many ways. Pen and Ink CRL Form 001(planned deviation for SOP), SOPs (Permanent exception documented in appendix), CRL Form 013 (one-time deviation approved by management), CRL Form 002 (new/modified policy) are all acceptable types of documents that can record the deviation and includes management approval.

The CRL's QMP policies are routinely revised to ensure quality, meet current practice, and address any issues/non-compliances as they arise to a lab-wide level. On occasion, it may be deemed necessary to document a decision that does not appear to line up with policy. In that case, CRL Form 013 must be completed and routed for approval. This form summarizes a planned action, usually of a technical nature, that may deviate from established policy, but is not to be confused with a nonconformance incident that occurs without intention.

Some QMP policies include exemptions which are typically applied to SOPs not covered under the laboratory's scope of accreditation. These exemptions are typically documented in the appendix of the SOP to which it applies.

2.3.6. Procedures

Following are the three (3) types of procedural documents used at CRL. For a current listing of all procedural documents, refer to Qualtrax (Document, Workflow, or Reports modules).

- SOPs – Procedural documents that prescribe an approved method through detailed instructions which are to be followed for established quality performance. At CRL, SOPs are used to document test method and general in-house policy instructions. They are available to clients in the intranet. More details concerning SOPs are available in section 9.4. (Standard Operating Procedures (SOPs) of this document.

- WIs – Instructions on how to perform a specific task associated with the laboratory's policy and/or procedures. WIs are used to describe internal policy or SOP general procedures and less likely to be of significant interest to clients so they are not available on the intranet. WIs are referenced throughout the QMP and SOPs when applicable.

- Workflows – See section 2.3.7.3.

2.3.7. Outputs

Following are the three (3) types of procedural document outputs.

- CRL Forms – The QMP, a few non-analytical SOPs and WIs incorporate CRL forms for internal records. Only a few forms such as CRL Form 003 (Data Request) and 008 (Analytical Request) are intended for client use while the rest are for CRL staff only. For this reason, only CRL Form003 and 008 is available to clients in the intranet. CRL Forms are referenced throughout the QMP and SOPs whenever applicable. For a current listing of output documents, refer to Qualtrax Report module (Master list)

- Spreadsheets – Excel spreadsheets are used by CRL staff for either calculation or tracking purposes. The CRL QA Coordinator uses spreadsheets to track schedules to comply with internal policy. For example, Performance Testing (PT) and supporting equipment schedules. Analysts use spreadsheets for calculation purposes. Refer to section 6.9, QA Documents Review (WIs, Forms, and Spreadsheets), for more information.

- Workflows – A workflow is a (automatic) procedure that documents the steps taken, which require input or output information, to complete an intended process. All workflows are created by a CRL system administrator(s) and generated through Qualtrax.

2.3.8. Electronic documentation

In accordance to the Managing Government Records Directive issued by the Office of Management and Budget (OMB) and the National Archives and Records Administration (NARA) (M-12-18) of August 24, 2012, the Chicago Regional Laboratory (CRL) of the United States Environmental Protection Agency (US EPA) Region 5 is incorporating a new electronic capture process for laboratory generated data along with its established paperless QA documents procedures.

Policy 013: The official records at CRL shall be maintained in an electronic format, i.e. paperless, wherever practical. An exception to this rule is work categorized as criminal investigation samples as the hard copy files remain the original documentation of observation and official record.

Paperless QA document procedures were incorporated in the CRL QMP version 2 in 2015. The Region 5 RMD Record Management Specialist for our section (CRL) approved of the Qualtrax QA document management system as the software is equivalently compliant to the Department of Defense (DoD) 5015.2, ISO 9001 accredited, and meets the short record retention schedules for these types of records. Technical records can have very lengthy record retention schedules, so it took some time to incorporate a robust electronic data management system that met requirements set by the Regional policy. Starting with the publication of QMP version 6, following GEN018 v3 and GEN032 v1, the laboratory will treat the electronic files of technical data as the official record. The signed and approved document containing the proposed Electronic Capture Process for Region 5 CRL Data packages is located in Qualtrax, ID 12367. The Region 5 Record Liaison Officer approved this proposal because the electronic data management systems used to archive CRL's technical records complies with the agency digitization standards under CIO 2155-S-1.0 and/or is DOD 5015.2 compliant.

Digital signatures are acceptable at CRL for internal agency purposes such as approving an SOP or workflow instance, but the signature must be authentic to the user in accordance to the Managing Government Records Directive issued by OMB and NARA (M-12-18) of August 24, 2012, Qualtrax requires approvers to login using an individual ID and password (and marks the approved document with a name and time stamp). The digital stamp in Adobe software is also acceptable because of the required login (to PC) function.

Electronic records for the most part are generated digitally without printing, but in some cases a hard copy is scanned. In such cases, the hard copy file should be discarded after confirmation that the scanned record is legible and it is officially archived via SOP GEN018 procedures.

Policy 013-01: Scanned electronic records must be legible and officially archived prior to discarding the hard copy.

For more details regarding technical or QA documents, refer to section 6.4.

2.4. Systematic Planning Processes and Client Required Quality Documentation

Policy 003: To submit samples at the CRL, clients shall submit documentation which include the following stipulations.

At EPA, the project manager (client) is responsible for documenting the project's expected data quality requirements in their approved QAPP.

Policy 003-01: Per CIO 2105.0 section 6, The U.S. EPA program requesting CRL analytical services shall have a project-level quality planning documentation (i.e. QAPP or other equivalent documents which include inspection plan, sampling & analysis plan and others) inclusive of a systematic planning process such as the Data Quality Objectives (DQO) process cited in CIO 2105.0 Section 6 and CIO 2105-P-01-0 Chapter 3. The project-level quality planning documentation shall specify the project quality goals or

objectives and measurement performance criteria per CIO 2105-P-01-0 Chapter 5. Such quality planning documentation must be completed and approved (as described in the program's applicable QMP) before samples are submitted to the CRL.

An exception to this Policy may be made, as determined and documented by EPA senior management, for time-critical emergency response activities. In such event, quality documentation shall follow sample submittal and, likely, sample analysis, as soon as feasible.

A copy of the client's approved project-level quality planning document (i.e. QAPP) including DQOs should be provided to the CRL through the CRL Sample Coordinator. The original documents remain with the client. The project-level quality planning document should provide details of the DQOs, as well as the exact number of samples, matrices, analytical services, sample volumes, preservation and holding times. Project managers are encouraged to use CRL expertise in developing analytical requirements for their DQOs and QAPPs. Note: Some QAPPs already exist for each of the Superfund START Contractors, State Superfund Programs, Cleveland Office, Water Enforcement and RCRA Enforcement. DQOs for inspections are commonly based upon facility permit limits, regulatory limits or similar program requirements.

In addition to the Agency policy, the CRL requires the following documents be submitted for sample analysis. Note: Sample work discussion between the client and CRL Sample Coordinator will clarify any questions regarding the stated documentation(s).

Policy 003-02: CRL clients shall submit an Analytical Request form to CRL prior to field work and include a Chain of Custody (COC) with samples upon sample delivery.

Analytical Request Forms (ARF) are provided to the clients by the CRL Sample Coordinator. The original ARF is located in Qualtrax/Documents/Quality Assurance/CRL Forms/Client Forms as CRL Form 008.

2.5. Data Verification

In accordance with the EPA QA/G-8 *Guidance on Environmental Data Verification and Data Validation* Chapters 2 and 5.1and the U.S. EPA Region 5 RMD QMP, CRL performs data verification on all the data generated internally. CRL does not perform data validation or quality assessment procedures.

For data verification procedural details, refer to sections 9.7.

3. **Organization and QA Management**

3.1. About the CRL

3.1.1. CRL's place within EPA

The United States EPA has ten regional offices, each with an environmental, analytical laboratory. CRL is a branch of the Resources Management Division (RMD) within EPA Region 5 located in Chicago, IL. The CRL supplies support services to the Region 5 Divisions and Offices including the Great Lakes National Program Office (GLNPO), other Regions, the states of Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin, Indian Tribes, and U.S. EPA Criminal Investigations Division (CID).

3.1.2. CRL facility

The General Service Administration (GSA) of the U.S. Government operates the building. The Management Assistant is the primary contact for reporting problems with the building. The CRL Data Coordinator serves as backup. EPA Regional Facilities Staff works with GSA to make modifications or necessary repairs.

Currently, the laboratory is undergoing renovation. Several laboratories are closed for demolition and construction.

3.1.2.1. Security

Building security is provided by contractors to the Federal Protective Service. The floor is secured with cipher locks on doors leading to active laboratories. The administrative area is accessed with key cards or through admission from someone inside.

CRL Staff should ensure visitors follow the following rules.

- All visitors to CRL shall sign-in and out with a record book located at the front desk.
- All non-government visitors shall wear a visitor's tag. Such tags are located at the front desk next to the sign-in record book.
- All visitors shall be escorted by a CRL staff member throughout their visit.
- All visitors shall wear safety glasses inside the laboratory area.
- Visitors may not be given any combinations to the lock pad doors nor be left unattended in the laboratory. Visitors to service and repair equipment must have a CRL staff person in the same or adjacent room at all times and wear an EPA tag. This is to ensure safety and security in the laboratory, as well as unassailable sample custody.

3.1.2.2. Lab Tours

Tour participants are constantly escorted. Tours will have a short safety lecture before entering the laboratory. Goggles or safety glasses must be worn in the laboratories, and will be furnished to tour participants if they do not already have them.

3.1.2.3. Environmental conditions

Environmental conditions – Construction is finished in some rooms where strategic measures and locations were taken in consideration to avoid possibility of cross contamination and/or to control the environment.

- *Clean Rooms:* 1037 (prep), 1039 (prep), 1041 (Hg), 1042 (ICP-MS). Rooms built with no metal surfaces or piping in order to keep metals from interfering at a very low level.
- *Environmental Chamber Rooms:* 1032, 1005. These rooms are controlled and monitored for specific temperatures and humidity.
- *Strategically Located Rooms*: 1008 (Air), 1010 (VOA), 1012 (SVOA), 1016 (Extraction). These rooms are purposely arranged in this order to avoid cross contamination. The test methods most sensitive to contamination from extraction preparation methods are located the furthest from each other.
- *Separate Air Supply System:* VOA laboratory room is on a separate air supply system than the rest of the laboratory in order to avoid cross contamination avoid interference with the sensitivity of the test method.
- *Properly Controlled Hoods*: All hoods are certified annually by the Chemical Hygiene Officer.

Specific environmental conditions, except as noted below, required by a test method are addressed in the relevant SOP. Note: All monitoring, controlling, and recording of refrigerators, freezers and smaller contained environments is covered under CRL SOP Gen025.

3.1.2.4. Floor Plan

Contact the CRL Director, CRL Deputy Director or Facilities Branch to obtain a recent floor plan. The laboratory is undergoing renovation with frequent changes to the configuration and uses of rooms

3.1.3. CRL staff structure

The CRL is organized into Supervisors, Coordinators (Quality Assurance, Sample, Data), CRL Sample Custodian, Management Assistant, and five analytical groups: Analytical and Inorganic (A&I), Gas Chromatography (GC), Mass Spectrometry (MS), Metals, Molecular Biology (MoBio), and Organic Methods (OM). The CRL Director reports directly to the Assistant Regional Administrator (ARA) for Resources Management. The CRL Deputy Director, CRL QA Coordinator, Organic Methods group, CRL Data Coordinator, CRL Sample Custodian and Management Assistant all report to the Director. The remaining analytical groups all report to the CRL Deputy Director who supervises the scientific laboratory staff. There are no other supervisors in the CRL. For staff listing and an organization chart, refer to Appendix A.

3.1.4. Staff experience

The CRL is staffed with experienced scientists holding a Bachelor's of Science degree to a Doctorate of Philosophy in the physical sciences. The staff's academic background includes organic chemistry, inorganic chemistry, computer science, computer automation and others. Many of CRL's processes are automated and computerized. For staff description and responsibilities, refer to section 3.7.

3.1.5. Services

3.1.5.1. Analytical services

The Region 5 CRL provides analytical services to Region 5 program offices. For a listing of current SOPs, refer to Qualtrax (Document or Report module). When the need arises, Region 5 CRL supports other EPA regions with analytical services, data verification, method validations, regional method program research, and sending chemists or receiving chemists for training. All clients are considered internal to the agency (EPA).

Project requests are received from the various Regional programs through contact with the CRL Sample Coordinator (SC) and by completing an analytical request form (CRL Form008). An understanding of what the laboratory can provide and client specific method request is reached prior to any laboratory activity being performed. For a complete list of general sample submission requirements, refer to section 8.2.1, General Requirements.

The CRL does not collect samples for EPA programs.

3.1.5.2. Drinking water certification program

Responsibility for the laboratory certification program was transferred from the Water Division (WD) Drinking Water (DW) program to the CRL in early 2017. These responsibilities include having Three (3) DW Laboratory Certification Officers that perform external (to the agency) audits for the DW program, and other related duties. One is an Organic Chemist, one is an Inorganic Chemist and the other is the Laboratory Certification Program Manager. Each one of these people must complete a DW certification officer training course for their relative field before performing any audits without supervision by someone who has this credential. It is recommended that Certification Officers should periodically (every 5 years) attend a refresher training. Analysis of public drinking water samples is not part of the duties assigned to this position.

3.1.5.3. Technical support

Besides sample analysis and method development responsibilities, the laboratory provides technical support in the following related areas.

• SOP and QAPP review • quality assurance audits of environmental laboratories • review of survey and monitoring proposals • review of existing and proposed regulations to assure appropriate analytical elements • expert technical support for TSCA, endocrine disrupters, pollution prevention, and biological programs • performs technical consultation on (facility) environmental data or analytical methods which can be included as part of enforcement case or site characterization/monitoring support.

3.1.5.4. Advice and expert testimony

The CRL's scientific expertise required to design and execute these analyses is also called upon to provide advice and expert testimony in Regional and National Program decisions, and civil and criminal litigation. This expertise is used to perform critical environmental analyses for sensitive enforcement cases. The reliability of the design, analyses, and results of projects undertaken by the Region requires adherence to sound science and requires rigorous quality control and quality assurance.

3.1.5.5. Center of Applied Science

The laboratory is a designated Center of Applied Science within U.S. EPA in the areas of water and toxic substances.

3.1.6. Methods used

Majority of CRL SOPs are based on regulatory methods and a few are written to meet client needs (not based on regulatory methods). A few SOPs are written exactly like the regulatory method while the rest contain minor modifications. When applicable, reference method deviations are documented in the appendix of that SOP to which it applies. Such modifications are documented and approved prior to use.

3.1.7. Clients

Samples are not accepted unless sponsored by EPA staff. All information produced in the CRL is provided to internal clients who may send it or request it sent to other parties, such as states or contractors.

Samples are only accepted from clients outside the U.S. EPA under the auspices of EPA program staff.

3.1.8. Other EPA branches

Purchasing, computer support, hiring and other support services are provided by other branches of RMD and Offices in EPA headquarters. These areas are governed by their own Quality plans and are beyond the scope of this branch and documents.

3.2. Scientific Integrity

3.2.1. EPA Scientific Integrity Policy

Policy 004: Each member of the CRL shall adhere to EPA's Principles of Scientific Integrity and the policies and procedures documented in this QMP.

EPA's Scientific Integrity Policy from EPA's Office of Science Advisory, February 2012. A copy of the EPA Science Integrity Policy document can be found in Qualtrax Documents under Quality Assurance/References/QMP.

It is essential that EPA's scientific and technical activities be of the highest quality and credibility if EPA is to carry out its responsibilities to protect human health and the environment. Honesty and integrity in its

activities and decision-making processes are vital if the American public is to have trust and confidence in EPA's decisions. EPA adheres to these Principles of Scientific Integrity.

The Principles of Scientific Integrity apply to EPA employees, whatever their grade, job or duties. They must:

- Ensure their work is of the highest integrity. This means that the work must be performed objectively and without predetermined outcomes using the most appropriate techniques. Employees are responsible and accountable for the integrity and validity of their own work. Fabrication or falsification of work results are direct assaults on the integrity of EPA and will not be tolerated.
- Represent own work fairly and accurately. When representing the work of others, employees must seek to understand the results and the implications of this work and also represent it fairly and accurately.
- Represent and acknowledge the intellectual contributions of others in representing their work to the public or in published writings such as journal articles or technical reports. To do otherwise is plagiarism. Employees should also refrain from taking credit for work with which they were not materially involved.
- Avoid financial conflicts of interest and ensure impartiality in the performance of their duties by respecting and adhering to the principles of ethical conduct and implementing standards contained in Standards of Ethical Conduct for Employees of the Executive Branch and in supplemental agency regulations.
- Be cognizant of and understand the specific, programmatic statutes that guide the employee's work.
- Accept the affirmative responsibility to report any breach of these principles.
- Welcome differing views and opinions on scientific and technical matters as a legitimate and necessary part of the process to provide the best possible information to regulatory and policy decision-makers.
- Adherence by all EPA employees to these principles will assure the American people that they can have the confidence and trust in EPA's work and in its decisions.

3.2.2. CRL Quality Policy statement

The CRL is committed to consistently provide timely data of known quality by using analyses methods that conform to our client's regulatory requirements and are compliant to ISO 17025, ILAC G-19, and Drinking Water accreditation standards. The laboratory professionally and effectively performs testing services that produce accurate and precise results through accredited test methods. We do all this by ensuring quality in the QMP policies set forth. All personnel must be familiar with and apply, as well as look to strengthen, the policies and procedures documented in the laboratory's QMP. The CRL also complies with the Forum on Environmental Measurements (FEM) Lab Competency Policy by holding an accreditation that meets or exceeds the requirements of ISO 17025 standards. Encouraging active participation of all employees in quality planning along with being an accredited laboratory contribute towards the continual improvement and effectiveness of the quality management system.

For CRL's quality objectives, refer to section 3.4.

3.2.3. CRL mission statement

The Chicago Regional Laboratory provides scientific expertise, training and environmental data of known and appropriate quality. Our contributions advance EPA's mission of protecting human health and the environment. Our work supports environmental decisions in the Region and the Agency in all program areas, public and private sectors, and Homeland Security. This Center of Applied Science maintains and expands its capabilities by developing methods for emerging compounds of concern and improving the performance of existing analytical methods. We meet our clients' needs through timely, complete, and scientifically sound responses.

3.2.4. CRL vision statement

We are committed to improving the quality of our data and the efficiency of our processes. We continually expand our knowledge and capabilities to meet new environmental challenges.

3.3. QA Responsibilities

3.3.1. All staff members

All laboratory staff members have Quality Assurance responsibilities. CRL staff is responsible for the quality of data provided to clients and for implementation of the CRL Quality System. All CRL staff have specific Quality Assurance/Quality Control (QA/QC) duties and are responsible for implementing the CRL quality system as appropriate to their daily work processes. For information concerning staff QA description, refer to section 3.7.

3.3.2. Management and FTE

The CRL Director and CRL Deputy Director allocate time and resources to support the laboratory quality assurance program as stated elsewhere in this document. 1 FTE is designated to the CRL QA Coordinator who performs 100% QA duties. Approximately 6 FTE is designated to the remainder of CRL staff members including management and Task Order Contracting Officer Representative (TOCOR). The 6 FTE is broken down by Chemist (4.5 FTE), management (0.2 FTE), and TOCOR QA/QC (0.3 FTE) associated work. 4.5 FTE was determined by the average total number of hours each Chemist spent completing, reviewing and updating QA/QC documentation, including QC analyses. Fifteen (15) Chemists X 30% (approximate weight of QA/QC duties verses non-QC sample analysis) = 4.5 FTE. A similar calculation applies to management and TOCOR but with a varied approximate percentage of QA work applied and does not include laboratory QC analysis. The total FTE of 6.0 represents the estimated allocation of time and resources which is reported in the Quality Assurance Annual Report and Work Plan. The stated plan is submitted to EPA Headquarters by the RQAM.

3.3.3. QMP responsibilities

The CRL QA Coordinator is responsible for training and making the CRL QMP available to all CRL staff and management. All CRL employees are responsible for reading and understanding the CRL QMP, including each revision update. By understanding the laboratory's policies, CRL employees are then responsible for implementing QMP policies and procedures in their CRL duties. All CRL employees should understand their QA/QC roles and responsibilities.

3.3.4. Performance reviews

Performance reviews take into consideration meeting QA turn-around times such as the 45-days to close out corrective actions. Details concerning performance reviews, appraisals, and recognition system are located in section 3.11.3.

3.4. Quality Objectives

3.4.1. Objectives of the quality assurance program are:

- To establish a framework for the laboratory emphasizing a commitment to quality and ethical laboratory practices.
- To monitor the operation and performance of the laboratory.
- To maintain in good status an ISO/IEC 17025 accreditation and in so ensure quality testing services.
- To identify problem areas quickly and provide a mechanism of corrective actions.

- To assure that the quality of analytical data generated by the laboratory is defensible to scientific and legal challenge.
- Ensure that all personnel are competent and qualified for the tasks they perform.
- Ensure all personnel familiarize themselves with quality system documentation in order to implement the policies and procedures in their work.

3.5. Organization Chart and Personnel Listing – Refer to Appendix A.

3.6. Personnel Goals

3.6.1. Goals related to skills

Personnel goals related to skills and training at CRL are formed by management and are based highly on instrumentation and/or test method needs. Management formulates the training goals on test method needs based on which test methods needs to be learned and/or instrumentation learning needs to support the test methods. Refer to the Technical Training subsection 4.5 of this document for other training need details. CRL only hires Scientists with a minimum of a Bachelor's degree in Chemistry, Physics, or Biological Sciences. Basic laboratory skills associated with those degrees are expected. CRL's training program for analytical staff include working with an experienced analyst and performing a Demonstration of Capability. These procedures can be found in the QA-WI007.

3.6.2. Education goals

The education goals at CRL are incorporated in the training goals (example: Demonstration of Capability) mentioned above as well as staff participation in the Laboratory Technical Information Group (LTIG) and technical conferences such as the Pittsburgh Conference (PittCon). Analytical staff is expected to attend monthly LTIG calls for their group and when possible attend the annual LTIG conference hosted by rotating EPA Regional laboratories. PittCon participation is based on available funds and needs. Other education goals are not defined by management as the federal government does not currently offer a continuing education program but the voluntary process of submitting an Individual Development Plan (IDP) is encouraged. Completing an IDP may help an individual with career and education goals. Refer to EPA Webforms to attain an IDP form (#EPA3140-31).

3.7. CRL Staff Description and QA

CRL staff are given as much authority as permitted by their position descriptions and the applicable regulations from the Office of Personnel Management.

3.7.1. Management & Supervision

Staff members are supervised by either the CRL Deputy Director or CRL Director. Both supervisors are familiar with the methods used by their staff members. The Division Director and CRL Deputy Director have authority to halt work, if necessary, and authorize work to resume.

3.7.2. CRL Director

The ultimate responsibility for the CRL Quality System rests with the CRL Director. The CRL Director is responsible for assuring that the CRL Deputy Director, Group Leaders and CRL staff implement the policies and procedures set forth in the QMP. The CRL Director also has responsibility for the ongoing evaluation and control of the CRL facilities, equipment, scientific developmental projects and staff under his supervision. The CRL Director is responsible for documenting all direct client contacts regarding samples (example discussion of sample results, analysis or method decisions) via client contact (CC) workflow in Qualtrax. The CRL Director reports to the Assistant Regional Administrator, Director of RMD.

3.7.3. CRL Deputy Director

The CRL Deputy Director (Technical Director) has the responsibility of assuring that appropriate Corrective Actions (CA) and Preventive Actions (PA) are taken by the scientific staff to assure scientifically sound products; tracking the progress and ensuring implementation and appropriate resolution (including effectiveness) of CAs; responding to nonconforming work; implementing the quality system at the bench level as well as assuring it complies with ISO 17025 standards; reviewing, approving (and therefore releasing) all criminal technical reports; documenting all direct client contacts regarding samples (example discussion of sample results, analysis or method decisions) via client contact (CC) workflow in Qualtrax, and responding to nonconforming work as stated in section 9.10. The CRL Deputy Director has the authority to refuse samples. Other paragraphs in this document outline the appropriate circumstances. The CRL Deputy Director reports to the CRL Director.

3.7.4. CRL QA Coordinator

The Quality Assurance (QA) Coordinator is responsible for oversight and documentation of the CRL Quality System, including assuring its compliance to ISO 17025 standards. The CRL QA Coordinator has no supervisory authority or duties. The CRL QA Coordinator is independent of laboratory analytical operations and reports directly to the CRL Director. The CRL QA Coordinator writes, maintains and monitors the implementation of this QMP and the effective operation of the Quality System. In addition, the CRL QA Coordinator conducts QA/QC training, assists the Lab Director with assessing the implementation of work processes, and is the system administrator for CRL's Qualtrax. Activities that support these duties are:

3.7.4.1. Performs internal SOP activity audits and writes the associated evaluation reports for all of the procedural technology types listed under the laboratory's accreditation scope. This audit assesses (data review and verification) and witnesses approximately 10% of released CRL data against the analytical SOP.

3.7.4.2. Leads and/or performs the annual internal quality system audit.

3.7.4.3. Writes, revises, approves, tracks, and maintains various quality assurance QA documents.

- Writes and reviews general standard operating procedures (SOPs) and quality assurance (QA) related work instructions that affect the entire laboratory.
- Reviews 50% of all laboratory analytical and general SOPs on annual basis so as to complete 100% of these type of document reviews every two years. In addition, performs reviews for unscheduled SOP revisions (not annual reviews) as needed.
- Reviews, approves, and tracking proficiency testing results.
- Reviews, approves, and maintains Demonstration of Capabilities records.
- Writes corrective action reports for both internal and external deficiencies which includes ensuring appropriateness, effectiveness, and completion of such actions.
- Reviews, writes, and tracks preventive action and nonconformance reports for the laboratory.
- Writes the laboratory's annual QA report and the portion of the RMD QA report that pertains to the CRL.
- Reviews, assesses, and revises quality policies and procedures documented in the quality management plan (QMP) and other QA documents for improvement, to meet accreditation needs, and address agency orders.
- Assists in writing Quality Assurance Project Plans (QAPP) for our laboratory projects funded by outside entities.

3.7.4.4. Provides staff training for annual QMP refresher, laboratory ethics/data integrity, criminal investigation samples procedures, Qualtrax functions, and/or other topics as needed.

3.7.4.5. Coordinating and monitoring the recertification of laboratory supporting equipment such as balances, temperature devices, mechanical pipettes, etc.

3.7.4.6. Reviews ISO/IEC 17025 and ILAC G19 accreditation standards to ensure compliance.

3.7.4.7. Reviews Accreditation Body (AB) policies including changes made to such documents and completes required paper work for assessment visits.
3.7.4.8. Updates LIMS files (J:\R5LIMS\ELEMENT6\SOP) to reflect SOP document updates.
3.7.4.9. Oversees all of the criminal investigation sample work including client contact documentation outside of Qualtrax (in a designated logbook which is securely stored at the CRL QA Coordinator's locked cabinet) and writing comprehensive and technical laboratory reports based on data review and verification performed.
3.7.4.10. Configuring and maintaining the Qualtrax software system.

3.7.5. CRL Sample Coordinator

The CRL Sample Coordinators are responsible for maintaining an analytical services (samples) schedule for CRL and Environmental Services Assistance Team contract for Superfund (ESAT). Throughout this document, CRL Sample Coordinator refers to staff assigned to coordinate CRL or ESAT projects. Activities that support these duties are:

3.7.5.1. Maintains the CRL sample analysis schedule by coordinating with Group Leaders, CRL staff, CRL Task Order Contract Officer Representatives (TOCORs) for ESAT services, clients and client representatives.
3.7.5.2. Reviews analytical requests for capacity, capability and appropriate methods, reporting limits and detection limits.
3.7.5.3. Ensures clients understand CRL requirements prior to submitting samples and reviews such documents for completion and filing. Before samples are accepted, clients submit an analytical request form to which they must meet the sampling requirements. The CRL Sample Coordinator receive this document along with the client sampling project plan and/or QAPP. Any concerns are discussed with the client before sampling starts.
3.7.5.4. Solicits client feedback concerning CRL performance and forwards complaints to the CRL QA Coordinator.
3.7.5.5. Generates and tracks an annual client feedback summary spreadsheet which is submitted to management at the end of the year for the annual review meeting. In order to launch the customer feedback survey, CRL Sample Coordinator is responsible for tracking the status of sample analyses.
3.7.5.6. Maintains all documentation concerning sample coordination, including but not limited to analytical request forms (G drive), QAPPs (G drive), sampling plans (G drive), client contact (Qualtrax), other requests and /or feedback (G drive), deviations to sampling plan (G drive and/or LIMS), etc.
3.7.5.7. Documents all client contacts requiring an action and/or decision to be made in the appropriate Qualtrax workflow (mainly the CC workflow, but can be NCR, CA, etc.).
3.7.5.8. Verifies LIMS work orders/sample analysis requests.

3.7.6. Analysts

Except for the OM group, scientific staff reports to the CRL Deputy Director. The OM group reports to the CRL Director. Scientific staff have QA responsibilities stated throughout this document. The following (below) is an attempt to summarize such responsibilities. Tasks include, but are not limited to:

3.7.6.1. Produce sound analytical data that meets the client's needs.

- Understand the project's data quality objectives (provided by the client or defaulted to SOP).
- Perform analysis in a timely, efficient manner using the most current and approved CRL SOPs along with good professional judgment.
- Ensure samples are analyzed under statistical quality control based on either regulation method limits or historical QC data whenever possible.

- Enter (or upload) all generated final data into the LIMS database, manually update LIMS data status to reflect the current data review step(s), and report the data according to CRL data package procedures (section 6.11).
- Ensure reportable data are verified by performing a technical review on either self-generated or peer's data and signing the final report and/or data verification checklist once all concerns have been addressed. By signing the data verification checklist, the second reviewer(s) are consenting to release data to the client.

3.7.6.2. Apply and adhere to CRL's quality system.

- Communicate with the CRL Deputy Director and/or CRL QA Coordinator about scientific and technical issues.
- Use (respond, process, meet deadlines, etc.) Qualtrax to its fullest capacity concerning QA documentation.
- Detect and report any irregularities in the analytical systems by the CAR and NCR procedures. A good example is any problems with samples that might not be detected by the controls built into the analytical systems.
- Coordinate and implement quality assurance activities, including organizing and planning activities to meet quality requirements consistently. For example,
    - Assure that all equipment and supplies used during test analysis are appropriate for the test method. This includes taking inventory, ordering, verifying ordered item(s) compliance to test method requirements (e.g. reagent and solvent grade), and storing of supplies.
    - Track individual Demonstration of Capability (DOC) certificates.
    - Coordinate to recertify applicable supporting equipment such as pipettes, syringes, balances, etc.
    - Participate in various workflow procedures such as CAR and NCR.
    - Review/update QA documents such as SOPs, spreadsheets, and WIs. Also review and submit comments to QA Coordinator or group designated member collecting responses for lab-wide QA document revision based on their group response.
- Recommend remedies or modifications of technical processes in order to improve performance in technical area.
- Develop new techniques or approaches as needed.
- Follow the CRL Chemical Hygiene Plan and Good Laboratory Practice (GLP).
- Adhere to good housekeeping practices to avoid accidents and chemical exposure.
- Participate in annual capital equipment planning for instrumentation and support equipment which may include writing a purchase request.
- Keep current on emerging environmental analytical issues and offering proposals to the CRL Deputy Director for continuous improvement.

3.7.6.3. Create and/or maintain SOPs by following internal policies.

- Document SOP deviations and obtaining approval prior to analysis preparation and analysis by following pen&ink procedures (see section 9.4.3).
- Keep up with the latest method reference updates and incorporate them in CRL SOP as needed. Regulatory method updates are incorporated into CRL SOPs as soon as possible.
- Act as a designated analyst or second reviewer for group SOPs by following SOP GEN006 responsibilities and instructions. This includes reading the SOP reference methods to ensure there are no deviations or acceptable deviations are documented as an appendix.
- Recommend SOP modifications and/or methods ready to be retired.
- Implement SOP revision (following approval) changes.

3.7.6.4. Coordinate with the CRL Sample Coordinator to meet client needs.

- Discuss analytical capacity and constraints with the CRL Sample Coordinator and CRL Deputy Director at Group meetings.
- Meet client expectations concerning analytical data delivery dates.
- Document all direct client contacts regarding samples (example discussion of sample results, analysis or method decisions) in the appropriate Qualtrax workflow (mainly the CC workflow, but can be NCR, CA, etc.).

3.7.7. Group Leaders

The Group Leaders are scientists who have agreed in their annual performance agreements with CRL management to accept responsibilities in addition to their analytical duties. In addition to Analyst duties as stated in section 3.9.6, Group Leaders document assigned work on a schedule and are usually the point of contact for their groups. Assignment of work as documented in group schedules is performed by the CRL Deputy Director during group meetings. Group Leaders also monitor technical problems and update Management on work load status; coordinate the annual SOP update and review process for the group and assists group members with determining method requirements and deviations; and coordinate the implementation of new polices.

3.7.8. CRL Sample Custodian

The CRL Sample Custodian reports to the CRL Director. The CRL Sample Custodian is CRL's Property Manager, primary Purchase Card holder and the main person to handle sample receipt. The CRL Sample Custodian's responsibilities include, but are not limited to:

3.7.8.1. LIMS entry, including sample login, tracking where samples are physically located and notifying analysts when samples arrive.
3.7.8.2. Operates a sample storage area and coordinates sample disposal with the Chemical Hygiene Officer (CHO).
3.7.8.3. Orders supplies, tracks receipt of supplies, manages general supply inventory, and stores supplies until needed. Storage areas for samples and supplies should be kept well organized to facilitate location of supplies and samples by others when the Custodian is not present.
3.7.8.4. Cross-checks sample information against the COC, CRL sample analysis table (provided by the CRL Sample Coordinator), and CRL sample preservation table for discrepancies upon sample delivery.
3.7.8.5. Properly carrying out Nonconformance corrective actions as stated section 9.10, Control of Nonconforming Work, and documenting it in the customer contact database.
3.7.8.6. Documenting all direct client contacts regarding samples (example discussion of sample results, analysis or method decisions) the appropriate Qualtrax workflow (mainly the CC workflow, but can be NCR, CA, etc.).
3.7.8.7. The CRL Sample Custodian is also the property manager for CRL.
3.7.8.8. Sample Custodian ensures sample WOs, or at minimum specific analysis sample(s) within a WO, have been verified prior to releasing samples for analysis.

3.7.9. CRL Data Coordinator

The CRL Data Coordinator reports to the CRL Director. Responsibilities supporting this role include but are not limited to the following. For more details, refer to SOP GEN018.

3.7.9.1. Checks the final data packages for administrative completeness by performing an administrative review. SOP GEN018 contains more details.

- Performs a final check on the final report prior to transmittal ensuring the accrediting authority logo is being used appropriately.
- Assures the required analyst signature (per client request) is documented on the final report prior to data transmittal.

3.7.9.2. Transmits preliminary and final reports to clients.

3.7.9.3. Records transmission dates in LIMS for timeliness tracking

3.7.9.4. Files all data packages including final reports in a secure storage area.

3.7.9.5. Documents all direct client contacts regarding samples (example discussion of sample results, analysis or method decisions) via client contact (CC) workflow in Qualtrax.

3.7.9.6. The CRL Data Coordinator is authorized to refuse to release any data that are not in compliance with the requirements of her checklist or otherwise not acceptable for transmission. The CRL Data Coordinator will bring any problems that are not resolved quickly to the attention of the CRL Deputy Director, CRL Director, CRL QA Coordinator or others in addition as appropriate.

3.7.10. CRL Groups

3.7.10.1. Analytical and Inorganic (A&I) - The A&I group performs analysis of environmental samples for mercury, nutrients, ionic species and physical parameters using wet chemical methods and instrumental techniques.

3.7.10.2. Metals - The Metals group analyzes for metals using inductively coupled plasma (ICP) and ICP-Mass Spectrometry.

3.7.10.3. The Gas Chromatography (GC) Group analyzes samples for specific organic compounds such as pesticides and PCBs using gas chromatography.

3.7.10.4. The Mass Spectroscopy (MS) Group analyzes for volatile organic, semi-volatile organic, and air toxics using gas chromatography/mass spectrometry methods and other mass spectrometric techniques.

3.7.10.5. Organic Methods (OM) - The OM group develops methods for compounds of interest to regional offices, Headquarters, and ORD. Currently, the OM group and the test method performed (OM SOPs) are not included in the scope of the laboratory's ISO 17025 accreditation and may be exempt from CRL policies pertaining to the accreditation requirements as noted throughout this document.

3.7.10.6. Molecular Biology (MoBio) - The MoBio group analyzes samples for endocrine disrupting chemicals using the quantitative polymerase chain reaction (qPCR) technique. Currently, the MoBio and OM group test method performed are not included in the scope of the laboratory's ISO 17025 accreditation and may be exempt from CRL policies pertaining to the accreditation requirements as noted throughout this document.

3.8. CRL Staff Designated Substitutes

3.8.1. CRL Deputy Director and the CRL Director - These two directors are the CRL supervisors and are designated as each other's alternate. When both supervisors are out of the laboratory for a day or more, one of the Group Leaders or analysts is designated as the Acting Director.

3.8.2. Staff absence - During staff absences of more than three (3) days in a row. One of the Directors may choose to delegate necessary duties to other staff members depending upon the circumstances and expected duration. In order to continue reasonable work flow during such absences, the Qualtrax "Out of Office" function will be implemented for some procedures containing more immediate processing need. This Qualtrax feature will be applied to the designated party for the following positions: CRL QA Coordinator, CRL Sample Coordinator, and CRL Deputy Director.

3.8.3. CRL Sample Coordinator - When the CRL Sample Coordinator is absent, the CRL Deputy Director or delegated staff member does sample coordination duties.

3.8.4. CRL Deputy Director - When the CRL Deputy Director is absent the CRL QA Coordinator approves data package narratives. In their absence, the Director or whoever is acting Director may approve data package narratives to release data.

3.8.5. CRL Sample Custodian - When the CRL Sample Custodian is absent, the designated alternate accepts samples and logs them in. CRL has two designated CRL Sample Custodian alternates.
3.8.6. CRL Data Coordinator - When the CRL Data Coordinator is absent, the CRL Sample Custodian releases data. The CRL QA Coordinator releases data if the CRL Sample Custodian is also absent.
3.8.7. Group Leader - When a Group Leader is absent for more than one week, the CRL Deputy Director or CRL Director designates a substitute.
3.8.8. In other sections of this document, the designations stated above apply whether they are mentioned or not.

3.9. CRL Interns and Senior EPA Employees (SEEs)

CRL has non-EPA employee scientists who work in its space aside from ESAT that assist with CRL sample analysis work. Currently, these include interns and senior environmental program (SEE) enrollee participant.

Policy 005: Any non-EPA employee scientist assisting with CRL sample analysis shall meet internal demonstration of capability qualifications (ADOC) to perform data analysis and in all data analyses must be secondarily reviewed by a qualified EPA employee prior to releasing data.

To have this level of transparency, such employees use a specific LIMS report template (designated for non-EPA) to report their data. This template includes identifying information (including a non-EPA title) about the person who performed the analysis and who from EPA reviewed it. In addition, Non-EPA employees should annotate in the case narratives of their data reports that they are not EPA employees and that the data has been reviewed by EPA prior to release. This policy also means that non-EPA employees are not to provide verification of data generated by EPA staff.

3.10. Environmental Services Assistance Team (ESAT)

3.10.1. Background

The ESAT team supports projects from the Superfund program, and is solicited and procured by EPA Headquarters for Region 5 Superfund Program. The U.S. EPA ESAT Regional Project Officer (RPO) is located in the Superfund Division.

ESAT operates under their own quality system, separate from CRL's but follows relevant sections of this QMP. Data generated by ESAT using CRL methods and equipment are outside the scope of CRL's accreditation.

ESAT contract staff use CRL facilities and equipment for analysis of samples for the Region 5 Superfund Division. ESAT analysts implement approved CRL or Field Analytical Support Program SOPs. There is a separate LIMS for ESAT; TechLaw Inc., the current awardee, reports data under their own identity.

3.10.2. Oversight

Currently three EPA staff at CRL serve as ESAT TOCORs. TOCORs issue technical directions to the ESAT contractors to assign projects, specify deliverables, and project hours, and provide feedback to the ESAT contract-level Project Officer on the performance of the contractors. One TOCOR is responsible for inorganic laboratory work, another for organic laboratory work, and another for the data support.

CRL TOCORs for analytical areas perform data package reviews. The organic and inorganic TOCORs perform a complete administrative (100%) and technical (10%) review on the ESAT data packages submitted. ESAT uses CRL data verification SOPs to review the data they produce. The administrative review assures all data package components are present and the technical review checks for data validity through verification.

The technical reviews are based on the analytical work and not CRL's QMP due to the fact that ESAT has their own quality system. CRL TOCORs provide the ESAT RPO with an evaluation of ESAT performance at monthly and yearly intervals.

For ESAT contract and sample planning work information, refer to 5.5.1 (analytical services) and section 8.2.3 (ESAT work) respectively.

3.11. Internal Communication

3.11.1. Meetings

Policy 006: Internal communication shall occur formally during Groups, CRL staff, and QA/Management meetings as described in the stipulations directly below.

3.11.1.1. Group meetings

Attendees: Respective group members and the CRL Deputy Director (or the CRL Director for Biology and OM groups). The QA Coordinator and/or Sample Coordinator may also attend as needed.

Frequency: The groups generally meet once every other week with the exception of A&I (meets weekly). The Biology and OM group meet upon need and/or CRL Director's request. GC, MS, OM, and MoBio, group ideally meet on the alternate week for the All Organics meeting for QA in order to catch up on the latest information.

Agenda: Management uses group meetings to schedule a group's work load as well as to ensure that the management system for CRL is properly communicated and effective. All groups discuss various topics including routine in-house work, deadlines, assigned tasks, various topic questions and/or clarifications, pending CAs, QA information, schedule information, and other general and management system related topics as needed. During this time management also helps to prioritize and re-enforce meeting client needs (which can include regulatory requirements).

Note: GC and MS groups also hold a QA-group meeting once every other week or as needed. The Deputy Director, GC, and MS group members are regular attendees. The QAC attends upon request or interest. The purpose of these meeting is to discuss quality assurance questions and issues that may affect the group within the group first, share information, coordinate or improve approaches where appropriate, and collaboratively problem-solve when needed.

3.11.1.2. CRL Improvement Team (CIT) meetings

Attendees: CRL Staff members, including management

Frequency: Currently CIT meetings are scheduled quarterly but are subject to change based upon requests and voting done during these meetings. Each meeting is normally schedule for 1.5 hours.

Agenda: The quarterly CIT agenda team is responsible for the agenda items. Routinely, discussions include present issues and making suggestions to improve the laboratory. Most importantly, the CIT provide a forum for discussion. CIT ground rules are normally read at the beginning of the meeting followed by management and other announcements and then other agenda items and/or activities.

Refer to section 11.2 CIT for other details.

3.11.1.3. QA management meetings

For annual management review meeting information, refer to section 10.3.

Attendees and frequency:

Attendees: The CRL Director, CRL Deputy Director, and CRL QA Coordinator

Frequency: Ideally, once a month

Agenda: The CRL QA Coordinator is responsible for the tentative agenda. Discussions include present quality assurance issues and making suggestions to improve the management system.

3.11.1.4. QA Lab-wide meetings

Attendees: The CRL QA Coordinator, CRL Deputy Director, and CRL staff members

Frequency: Once a month

Agenda: The CRL QA Coordinator is responsible for the tentative agenda. Discussions include announcements, present quality assurance issues, and/or upcoming policy/procedural changes. As needed, all topics are open for discussion.

3.11.2. Presentations

Sharing professional presentations with co-workers gives staff members the opportunity to be informed on activities in the laboratory. Often staff practices their presentations at the CRL, allowing others to learn more about development projects in the laboratory.

3.11.3. Performance reviews

All employees of the CRL are required to have formal, yearly, performance appraisals where their performance standards are reviewed and revised. This evaluation is based and documented on an EPA Performance Appraisal and Recognition System (PARS) record which include the submittal of any voluntary IDPs.

All technical staff have statements included in their performance standards that they are to implement this quality management plan. In addition, the CRL QA Coordinator has specific QA responsibilities incorporated into his or her performance standards. All staff are required to attend training on the CRL Quality Management Plan, yearly. Their attendance is documented with signatures. Their responsibilities for implementing the quality system are emphasized throughout the training.

Performance appraisals and award system justification are also used to highlight the importance of individual staff member's activities. Part of the performance appraisal includes management discussion on meeting the client's needs (which may include regulatory requirements) and its importance.

In addition to the end of the year evaluations, discussions are held in the middle of the fiscal year to evaluate performance and foster discussion of any problems. Documentation of these reviews is held in privacy by our Regional personnel office.

The CRL Director holds midyear and end-of-year performance reviews with immediate office staff and the CRL Deputy Director holds these reviews with the scientific staff. All staff are kept informed of current events, project status and issues through Email and the Region 5 Intranet.

3.11.4. Management

CRL management has an open door policy. Staff is welcome to talk to their supervisors at any time with concerns. For laboratory ethics concerns, contact the CRL Deputy Director immediately.

3.11.5. Coordinators

Analysts are required to communicate with the CRL Sample Coordinator, CRL QA Coordinator, and CRL Data Coordinator. Contact the CRL Sample Coordinator regarding client issues, including matrix problems, other sample problems and schedule revisions. The CRL QA Coordinator should be consulted with any QA related issues. Contact the CRL Data Coordinator concerning data transmittal issues.

3.12. Standard of Service

3.12.1. Communication

3.12.1.1. Project needs

All data is intended to satisfy the customer's data requirements documented in their project-level quality document (i.e. QAPP). The goal of the CRL is to deliver analytical data, scientific expertise, and technical skills to meet the needs of our clients now and in the future. In order to do so, open communication and cooperation between the CRL and its clients is a necessity.

3.12.1.2. Project visibility

Another aspect of communication between CRL and its clients is visible during project planning. CRL staff participates (as requested) in DQO and QAPP planning by lending their expertise on analytical methods and capabilities.

3.12.1.3. Client notification – For client notification detailed information, refer to section 10.8.2.

3.12.2. Timeliness

Policy 007: CRL staff members shall adhere to the following timeliness stipulations.

3.12.2.1. Data package delivery

The CRL client service goal is to have 90% of the data packages delivered on or before the negotiated due date on an annual basis. Our LIMS is used to track this time. Ideally, each quarter preliminary calculations are provided to analysts with information on the analyses used in the calculations. If changes are needed, the CRL Sample Custodian makes changes before the final quarterly report is calculated. The annual report is generated using the same data as the quarterly reports. The quarterly and annual timeliness reports are delivered to the CRL Director who uses them in his annual report to the Division Director.

3.12.2.2. LIMS and due dates

Each work order in the LIMS represents samples that arrived from a project on a single day. Samples arriving on different days will have different work order numbers and differing due dates. If the samples arrive within less than a week, the due date for all samples may be changed to the due date of the last work order. If the samples are spread out over more than a week, the assigned due dates will be used or the client consulted for modification of the due date. Due dates falling on a weekend or holiday will always be due on the first business day after the due date.

3.12.2.3. Successfully meeting due dates

A due date is successfully met when analytical results have been transmitted from the laboratory. The timely analyst allows enough time for the second analyst review, plus two business days for the CRL Data Coordinator's review and data transmission.

3.12.2.4. Due date extensions

Due date extensions are made when it is demonstrated that equipment was malfunctioning, supplies were not available to perform the analyses, workload was an issue, including but not limited to, priority projects, etc. As soon as equipment problems are suspected that might delay timely delivery to the client, the CRL Deputy Director should be notified. A request for change of due date should be given to the CRL Deputy Director at least one week before the data are due. The client will be notified and the due date will be changed when the CRL Deputy Director or CRL Director approves a change. Due dates will not be changed to account for vacations, or absences. Circumstances other than technical problems may be discussed with the CRL Deputy Director and CRL Director and left to their discretion. Under the irregular circumstance of laboratory shutdown, extensions will be planned and discussed with clients.

3.12.2.5. Quick TAT

Data may be requested on a short time frame with quick turn-around times (TATs). If this request does not interfere with current analyses already in progress, the CRL will accommodate the request. If the request interferes with analyses already in progress but it is considered priority or an emergency, the request must come from a Division Director. The program Division Director would ask the RMD Division Director to direct work stoppage on current samples at CRL to accommodate emergency work.

3.12.3. Confidentiality

Policy 008: CRL shall take measures to protect client's sensitive information.

3.12.3.1. FOIA and CBI

All information produced by the CRL is open to citizen requests for government information under FOIA, unless the information is protected by confidential business information (CBI) statement or is enforcement confidential.

Policy 008-01: To handle CBI documents, staff members shall be CBI certified.

Currently, the CRL Data Coordinator is certified to handle CBI documents if needed. RCRA and TSCA programs are those that are most likely to have CBI requests. These usually cover data provided by the regulated facility for comparison with CRL results or for technical review. Since there is no anticipation of project for sample analysis requiring CBI certification, CRL staff members will only acquire abbreviated CBI training as needed. CRL sample analysis services requiring CBI certification was over fifteen (15) years ago.

Policy 008-02: Staff members shall refer any media requesting information to the Regional Administrator's Public Affairs Office.

If CRL staff is contacted by a news agency, Regional policy is to refer the contact to the Regional Administrator's Public Affairs Office (1.800.621.8431 toll free; local 312.353.2000, or r5hotline@epa.gov) for information. Results, samples and data are not to be discussed with anyone outside EPA. Refer questions on results to the program office or Public Affairs office.

3.12.3.2. Major examples of USEPA programs served are:

- Superfund Amendments and Reauthorization Act (SARA; SF)
- National Pollution Discharge Elimination System (NPDES)
- Great Lakes National Program Office (GLNPO)

- Water Quality Management (WQM)
- Resource Conservation and Recovery Act (RCRA)
- Toxic Substances Control Act (TSCA)

3.12.3.3. Enforcement sensitive

Sample projects can be designated as civil, enforcement, or criminal.

Policy 008-03: Sample projects designated as criminal shall follow the CRL Criminal Investigation Samples procedure, SOP GEN007.

3.12.3.4. Data file storage names

Since the LIMS work order sheets contain all of the necessary client and case information, such details (client names or projects) should not be referred to in any other supporting data, especially bench sheets and raw instrument data. Since CRL's clients are internal to the agency and the used electronic data storage systems and share drives/sites are secure and limit user rights appropriately, naming conventions for electronic pathways (can be set up by programs or projects in order to ease data transmittal. This does not apply to CIS work where all analyst files are limited to the CRL work order ID.

Policy 008-04: With the exception of CIS type work, internal agency drive folders and files may be set up by project name so long as each folder limits viewers appropriately.

4. Qualifications and Training

4.1. Staff Qualifications

4.1.1. Staff qualifications are determined using position descriptions and required skills as outlined in Federal Personnel Regulations. Only applicants meeting the education, experience and course work requirements are interviewed or have their applications reviewed by Lab supervisors. Proof of degrees earned, course work and experience are a condition of employment at EPA. All documentation is held in confidential files in the Human Resources office. Personnel certifications for education and background are performed by Human Resources according to OPM guidelines.

4.1.2. CRL Director – Minimum qualifications are a Bachelor's degree in a scientific or engineering discipline, a minimum of three years of laboratory experience, and a minimum of one year of supervisory experience.

4.1.3. CRL Deputy Director – The CRL Deputy Director's minimum qualifications are a Bachelor's degree in Chemistry, engineering, or physical sciences, with a minimum of 24 college semester credit hours in chemistry and a minimum of two years of laboratory experience.

4.1.4. Quality Assurance Coordinator – Minimum requirements for the CRL QA Coordinator are a Bachelor's degree in Chemistry or other scientific or engineering discipline, three years of laboratory experience including one year of experience in quality assurance practices.

4.1.5. Technical Staff - All technical staff must have documented Bachelor's or advanced degrees.

4.2. Demonstration of Capability (DOC)

Policy 010: CRL Chemists and/or instruments shall demonstrate their capabilities to perform analytical services according to the stipulations provided.

4.2.1. Policy Stipulation

A Demonstration of Capability (DOC) refers to either an analyst demonstration of capability (ADOC) or an instrument demonstration of capability (IDOC) which are performed in order to prove competency. An ADOC is directly tied to individual analyst per analytical SOP, preparation technique and matrix. An IDOC is instrument dependent and can qualify an analyst as part of its procedure. Therefore, an IDOC may be used to satisfy an ADOC. P&A samples are required to demonstrate the precision and accuracy of all SOP analytes. For DOC procedures, refer to QA-WI002.

4.2.1.1. IDOC

An IDOC must be completed for any new instrument (preparation/analytical) and any time there is a significant alteration at the analytical instrument or method level (change in instrument type, operating conditions, or test SOP). If the method or instrumentation used for preparation/analysis is altered in a way that can be reasonably expected to change its sensitivity, then an IDOC applies: Re-determine the initial MDL (and then restart the ongoing data collection) and perform a P&A study. Note: For cases where there is a question, confusion, or disagreement regarding how the method or instrumentation alteration affects the sensitivity of the method/instrument and the Deputy Director determines that an MDL study is not necessary, CRL Form 013 must be completed and routed for final approval.
An IDOC must be approved for the instrument in use prior to analyzing data for clients. For DOC acceptance criteria, refer to QA-WI002.

IDOC procedure requires a minimum of an MDL and a Precision and Accuracy (P&A) study. A new matrix to an existing SOP will require an IDOC unless it is a one-time occurrence in which case a P&A study is requested time permitting. New methods may require additional procedures such as analyzing samples side by side in a comparison study, participation in an immediate PT study, etc. For additional information refer to the Method Validation Procedures subsection 4.3 of this document.

4.2.1.2. ADOC

Analysts may operate equipment (including analytical instrumentation) only after they have been trained on such equipment. An approved ADOC certificate assures that only trained analysts operate the equipment associated with the SOP for that DOC. ADOCs are required for any analyst before reporting data from a CRL SOP. An initial ADOC (analyst's very first ADOC) must be approved before analyzing any client data. All DOC documentation (via workflows) should be submitted in a timely fashion as the certification expiration date is based on the date of analysis or date of submittal for historical P&A data. An ADOC lapses after one year and should be repeated prior to reporting data. To remain qualified, an ADOC is required on an annual basis per SOP, preparation technique, and matrix. Qualified analysts may review data for similar methods to which the ADOC belongs to.

ADOCs are required for given active, preparation techniques in a SOP. When SOP preparation techniques are substantially similar to one another, no ADOC is necessary provided the criteria are in QA-WI002 section 2.4 are met. In the case where an analyst assists during the method's preparation steps, the assisting analyst must be qualified on the preparation steps including an approved DOC workflow instance. If not qualified, the assisting analyst may perform basic preparation steps provided a qualified analyst is overseeing the work and spikes the appropriate samples (BS, MS, etc.). For interpretation issues or questions regarding support roles versus qualified analyst, contact management. TCLP Note: While there is no DOC requirement (no suitable procedure) for TCLP, an analyst needs a current ADOC for sample preparation and instrument analysis of a given sample matrix to which the leachate will undergo.

The analyst performing the second data review must have direct knowledge of the analytical equipment used to generate the data. An ADOC in the same technology (to the data being reviewed) is considered acceptable experience to be a second reviewer. The second analytical reviewer should be familiar with the analytical method but need not be qualified by a current DOC.

4.2.2. Procedure

For all DOC procedures, including approvals, routing, maintaining and tracking records as well as acceptance and failure to meet ADOC acceptance criteria instructions, refer to QA-WI002. Note: MDL acceptance criteria is documented in QA-WI-005.

4.3. Method Validation (new SOP)

4.3.1. General requirements

New methods and equipment must be demonstrated to perform as expected by following method validation procedures. Data should support the supposition that a new method or equipment is precise, accurate, and robust. Before an analysis can be reported, any new method or equipment must have an IDOC completed by a qualified analyst (sufficiently trained to perform the test) equipped with adequate resources (equipment/instruments, references, etc. in order to perform the analysis).

Method improvement, development and validation are planned activities, documented in the CRL schedule during group meetings. The CRL Deputy Director assigns a qualified analyst to perform the work and monitors progress on developmental activities. SOPs and SOP revisions document the final outcome. Before use to provide results to a client, every CRL method must have an approved SOP.

The method validation procedures stated below applies whenever there is a procedure establishing a new technology or instrument technique not used before, a new method to CRL, and/or as determined after consulting with the CRL Deputy Director. Method validation is not necessary for an existing SOP upgrading instrumentation unless the changes to the instrument are significant. When in doubt, consult with the Group Leader and CRL Deputy Director. If determined that method validation is needed, the following procedure must be done before that SOP may be used for analysis at CRL.

4.3.2. Non-Standard Method

When using non-standard methods, a method that is not promulgated in the Federal Register, Program guidance, or standard analytical references, CRL will first discuss it with the client to consider project specifications and/or requirements as well to understand the laboratory's procedure for creating a new method including the use three times the standard deviation of four or more P&A samples to establish control limits on a Laboratory Control Sample (LCS). These values are preferably from more than one analytical run and may be a compilation of values from several developmental, analytical sequences. All other appropriate quality control limits would be established using similar statistics. For instructions on creating a new SOP, refer to CRL SOP GEN006 (SOP for SOPs). Note: New SOPs must be reviewed by the Chemical Hygiene Officer.

For Method validation procedures, refer to QA-WI009.

4.4. Mandatory Training

Policy 009: CRL staff members shall complete appropriate training as described in the stipulations below.

4.4.1. General Information

Physical attendance to training is required for CRL staff unless approved by the CRL Deputy Director or CRL Director in which case a traditional or alternative make-up training procedure can be implemented. Traditional make-up trainings are ones in which the original presentation is completely redone by the presenter specifically for the missed attendees. An alternative make-up training procedure example is one where the staff member reviews the presentation slides and handouts, followed by contacting the presenter for

any follow-up information and/or questions. Signed attendance sheets and/or Qualtrax training actions document that the employees have received the training. New hires are included in the yearly training. Supervisors attend the training and emphasize important points. The trainings not discussed in the details following are addressed by other EPA officials via mass email messages and include directions on how to take the trainings and due dates.

4.4.2. CRL Training List

The following CRL training list are mandatory as it applies per description and staff member. Additional training details are described in section 4.2.3-4.2.6. Agency training are in addition to the list provided.

- Laboratory Safety
  - 24-hour initial and 4-hour annual refresher for all scientific staff
- Radiation Safety
  - 8-hour initial training and 2-hour biennial refresher for affected staff
- QMP Training/Refresher
  - QMP updates and refresher training for all CRL staff, annual
- Laboratory Ethics
  - Laboratory ethics training including data integrity for all CRL staff, annual
- Required for assigned Contract Officer Representatives (COR):
  - COR Basic Training
  - Multiple, varied COR Continuous Learning Trainings
  - Recertification needed every two years
- Purchase Card Training
  - For Purchase Card Holders and Approving Officials, recertification as required
- DOT training on shipping
  - For CRL Sample Custodian, recertification as required
- CBI training
  - For CRL Data Coordinator, recertification as required
- EMS Training
  - Environmental Management System training is mandatory for the laboratory representative (DD) and the representative's back-up.
  - Training frequency is determined by the agency
- Good Laboratory Practices (GLP)
  - Annual training for all scientific staff
- Science Integrity Policy Training
  - Required attendees and frequency is determined by the agency

4.4.3. Stat Staff Training When Learning a New Analytical SOP

When staff members learn a new analytical SOP, many steps are taken to assure proper training. Prior to starting a new analytical SOP, the trainee must have read the QMP and taken all of the appropriate trainings (safety, ethics, etc.). Then, the trainee must read the SOP and shadow an experienced analyst before attempting to perform a Demonstration of Capability. Refer to QA-WI007 outlining the procedure taken when learning a new analytical SOP.

4.4.4. Laboratory Ethics with Data Integrity

Whenever a suitable webinar is available by a vendor, CRL purchases Ethics Training to meet (or help meet) the laboratory Ethics with Data Integrity requirement. In the past APHL's Laboratory Ethics webinar have been successful. All staff members attend the webinar together in the main conference room and discuss highlighted points or questions relevant to CRL. If the webinar lacks information, the CRL QA Coordinator and/or management elaborate. The CRL QA Coordinator schedules this training. In the absence of a suitable webinar for laboratory ethics, the CRL QA Coordinator does the training.

4.4.5. The QMP

Annual training on the Quality Management Plan is mandatory. Staff is responsible for reading the QMP including revision tracked changes once it is released. Normally, only one (1) Make-Up training class is available per year and is scheduled prior to the all hands training. Alternative make-up training is a decision left to management.

4.4.6. Safety

CRL analysts are required to take initial and 24-hour laboratory safety training prior to beginning laboratory work and annual 4-hour refresher safety training. The current safety training requirements are described in the CRL Chemical Hygiene Plan. Safety training for new staff will be included in the CRL orientation within their initial 30 days. Refresher safety training will be required annually for all analysts performing work in the chemistry laboratories.

Contractor and Grantee employees are required to have initial and annual refresher laboratory safety training. The Grantor, Contract Officer, or Regional Contract Representative(s) are required to notify the CRL Director of all new staff within 30 days of their start work date.

The CRL Chemical Hygiene Officer (CHO) is responsible for laboratory safety training records for all laboratory staff.

Policy 009-01: CRL staff members must follow safety rules and good laboratory practices (GLP). This policy is effective on the date CRL SOP GEN031 v1 is published.

It is important that CRL staff members follow laboratory safety and GLP using personal protective equipment (PPE) as well as the rules and practices outlined in the current chemical hygiene plan and SOP GEN031 (GLP). See additional SOP details in the next section. For tracking purposes, policy noncompliance incidents will be documented under the NCR workflow using the personnel initials and date followed by "(safety)" or "(GLP)" in the title.

4.4.7. Good Laboratory Practice (GLP)

Once the QMP v5 document is published, scientific staff must read CRL's GLP SOP and take the associated NDVR test annually. The annual safety refresher training may also include some discussion concerning GLP based on need and consultation with the QA Coordinator. The NDVR test for the GLP SOP GEN031 is scheduled to coincide with annual safety refresher training.

4.4.8. Specific scientific training

Specific scientific training is based on time and funds availability.

- Technical Skills
- Quality Assurance
- Quality Assurance in Contracts

4.4.9. Evaluating training effectiveness

CRL trainings are evaluated for effectiveness during the annual management review. During this event, a list of annual CARs and NCRs are reviewed. In specific, the description and root cause of the CAR/NCR occurrence are reviewed to determine whether they were due to an ineffective CRL training, isolated incident, or other reason. Note: This is natural step in the CAR/NCR procedure when determining the root cause of an incident, so it should already be documented in the workflow instances. The list of CARs and NCRs are typically documented in the QA Coordinator's annual QA

report. If none or a few of the CAR and NCR incidents are due to an ineffective CRL training(s), then the associated training(s) are considered effective or partially effective, respectively. If multiple CAR and NCR incidents are due to an ineffective training, then the associated training is not considered effective resulting in a revised training approach and/or remedial training if needed.

4.5. Technical Training

At CRL, technical training is performed by identifying training needs using EPA Individual Development Plans (IDPs), mandatory in-house training, and vendor training of new equipment whenever possible.

4.5.1. Individual Development Plan

The CRL uses EPA's system for employee development, which includes IDPs that identify training needs. The IDPs are developed along with performance standards when a new employee is hired. The plans may be reviewed and updated annually. IDPs are voluntary but encouraged.

4.5.2. In-House Training

Analysts are initially qualified by education with a minimum of a BS degree in Chemistry, Physical or Biological sciences. Every new analyst is trained, regardless of education and outside experience, in the individual analytical procedures by a designated analyst. A designated analyst is a CRL staff member with at least one year on the job in that analytical specialty, who has demonstrated proficiency with the method and instrument. Through Analyst Demonstration of Capability (ADOC) studies, all CRL analyst capabilities are determined initially and verified yearly. LIMS Training is part of the analyst demonstration. Work Instruction, QA-WI002 includes requirements of the procedures.

4.5.3. Training by Equipment Vendor

Technical training on new equipment should be done by the vendor whenever possible. PR preparer should include technical training in the purchase price of new item whenever it is offered.

4.6. Cross Training

4.6.1. Each analyst must help meet our client's needs by training as an alternate analyst on routinely used methods. These skills help maintain continuity through vacations, sick leave and other absences of the designated analyst. Each alternate analyst will be required to demonstrate competence. The capability is documented in a Demonstration of Capability certificate. Refer to section 4.4 for more details.

4.6.2. The CRL Sample Coordinator will plan unusual method requests so that the analysis does not conflict with planned absences of the designated analyst. Training for alternate analysts on unusual parameters will occur when samples requiring those parameters are available.

5. **Procurement of Items and Services**

5.1. Purchase Quality and Traceability

CRL is equipped with all measurement, subsampling, supporting equipment and instrumentation required to correctly perform SOPs. Any items needed to meet SOP requirements shall be ordered following SOP GEN026 as soon as possible and preferably before samples arrive. CRL equipment and supplies purchase (card and requests) policy is bounded by the following stipulations, including designated personnel and responsibilities. For procedural details, refer to GEN026.

5.1.1. Official personnel

CRL Sample Custodian is the Purchase Card Holder (PCH) for CRL. The PCH's back-up is currently a Chemist. The receiving official for CRL is also the CRL Sample Custodian.

5.1.2. Purchase quality

Policy 011: The CRL representative initiating any procurement request (PR) or purchase card order request shall document (via the purchase request) the quality expectations and ensure that the level of quality required is provided by the supplier.

For procedural details, refer to SOP GEN026 sections 8.1.1 & 8.6.

Policy 011-01: When a supply or service negatively affects the quality of the testing and calibration, the analyst who discovers it shall complete CLR Form011.

After the form is reviewed by the CRL QA Coordinator, the updated list will be sent out to all analytical staff members.

5.1.3. Standard and Reagent verification and traceability

The reagent water supplied through internal piping meets requirements for ASTM Type II water. The quality of the water for analytical purposes is verified through use in method blanks.

Policy 011-02: All vendors providing standard reference materials, especially when used to calibrate instruments, must be traceable.

For vendor traceability requirements, refer to section 5.6.2. Equipment & Quality.

Policy 011-02-01: All standards, reagents, and reference materials used shall contain a LIMS ID (one per container), be recorded in a LIMS bench sheet, and submitted with the data packages.

5.1.4. SOP appropriate and requirements

Policy 011-03: All Chemists analyzing samples shall assure that all of the equipment and supplies used during test analysis are appropriate and correctly stored for the test method.

These responsibility includes taking inventory, ordering, verifying ordered item(s) compliance to test method requirements (Reagent and Solvent grade), and storing of supplies as needed and/or required. Ordered item verification to meet test method requirements is documented on the order invoice or receipt by the analyst. For this verification documentation procedure, refer to GEN026 section 8.7.

5.1.5. Purchase request review and approval

Policy 011-04: All purchasing documents shall be reviewed for technical content and approved by the CRL Deputy Director (PCH Approving Official) prior to being released to the PCH.

If the purchase documents do not contain technical content (such as most administrative supplies), then the review of technical content does not apply.

5.2. Instrumentation & Supporting Equipment

Policy 028: Analytical instruments and supporting equipment shall adhere to the following traceability and verification stipulations.

Analytical instrumentation (via LIMS) and supporting equipment (via Qualtrax) identification, including but not limited to manufacturer's name, model and serial number are all entered into LIMS and/or Qualtrax by the CRL QA Coordinator for tracking. New analytical instrument quality is verified by the procedures referenced in sections 4.5. SOP primary analysts are responsible for assuring updated equipment instructions (use and maintenance) are available in an easily and ready retrieval location as documented in the relevant SOP.

CRL does not allow their instrumentation and supporting equipment to go outside of the laboratory. Should an exception ever be made to this regard, the instrument and/or supporting equipment will be checked and shown to be satisfactory before being returned to service.

5.2.1. Supporting Equipment Certification

Policy 028-01: All supporting equipment used for sample and/or standard preparation that are subject to potential change in calibration must be calibrated by an ISO 17025 vendor prior to use and recertified according to the specific schedules stated below.

New supporting equipment must be calibrated for proper certification prior to being placed in circulation for use. For new equipment arriving with an ISO 17025 certificate meeting the QMP vendor requirements, the following consideration is applied to the start of its recertification frequency and schedule as documented in SOP GEN026. Supporting equipment that is considered sensitive to potential change in calibration shall follow the established frequency and schedule for recertification. Such items include, but are not limited to, non-glass analytical pipettes, balances, and class 1 standard weights. Other supporting equipment, such as thermometers, that are not easily subject to a change in calibration may fulfill the life of the newly purchased certificate to its expiration date before starting the established in-house recertification frequencies and schedules.

Supporting equipment used for sample and/or standard preparation that are subject to potential change in calibration are recertified according to the frequency and schedules listed in GEN026 (Equipment & Supplies) Section 6.5. After supporting equipment is returned to the laboratory from being serviced, the associated paperwork and certificates will be examined for defects and to ensure the verification (performance accuracy) "passed." When supporting equipment is overloaded, mishandled, shown to be defective/outside specified recertified limits or gives suspect results, a control of nonconforming work (QMP section 9.10) will be initiated. All supporting equipment records are maintained in Qualtrax.

Supporting equipment may be serviced in-house or off site. The CRL is not in the practice of shipping analytical, non-glass pipettes because they are sensitive to potential change in calibration. These pipettes are routinely picked up/dropped off by the vendor for servicing. Should the pipettes need to go outside the laboratory, ensure they are packed properly and/or with the pipette's original box. If analytical, non-glass pipettes travel outside the laboratory for purposes other than recertification services, the pipettes should be checked on an analytical balance with DI water and shown to be satisfactory before returning to use. For instructions on how to check these pipettes, refer to QA-WI011.

Glass syringes are not required to be recertified. Based on the data collected by CRL dating back several years, syringes are not subject to potential change in calibration unless there is an obvious (clogged needle or leaky syringe) issue in which case the syringe must be repaired to its normal state or taken out of circulation. CRL's recertification records support this finding. The syringe recertification certificates demonstrate that recertification never failed unless it had an obvious issue.

A Standard NIST-traceable calibration service is acceptable for all reference use thermometers.

The supporting equipment identification for chambers, balances, ovens, furnaces and non-glass pipettes used shall be documented on the LIMS bench sheet (or equivalent) in use. The standard weight set ID (s/n) used to check balances shall be documented in each entry made (including initials and date) in a balance logbook. All supporting equipment shall have a unique ID and be labeled with recertification status including calibration date and expired (or due) date whenever possible.

5.2.2. Balance weight tolerance

Policy 028-02: All balances shall be checked with class "S" weights on the day of analysis to cover the range of the desired weight(s) to be used, including the tare mass if applicable.

Balance weight tolerance criteria can be found in SOP GEN026 and should be applied. For daily reference purposes, the balance weight tolerance criteria should be documented in the beginning of each logbook assigned to individual balance(s).

5.2.3. Glassware

Glassware is defined as all glass or plastic graduated cylinders, volumetric flasks, and pipettes used as measuring devices in the laboratory. All stated measuring items are herein referred to as "glassware."

Policy 028-03: To avoid confusion and remain consistent about the type of glassware used in the laboratory, CRL shall only use Class A glassware unless it's not used for volumetric measurement.

When glassware is not in use as a volumetric measurement device, the article shall be permanently labeled with the reason for exception or kept in a separate location and appropriately labeling that area. Labels must be clear and precise. Purchase card holder are not allowed to order non-Class "A" glassware unless the CRL Deputy Director specifies approval and should consult order requesters when in doubt. The state glassware policy is effective June 26, 2013.

5.3. Purchase Requisition Origination

Refer to CRL SOP GEN026 section 8 for purchase requisition origination and procedure and documentation.

5.4. Budget Preparation and Monthly Monitoring

Laboratory Supplies and Laboratory Instrument Maintenance and Repair Contracts comprise the CRL Supply budget. These expenses are apportioned to various program accounts by Headquarters OARM at the beginning of the FY. They are then shared with the Regional Labs according to prior year work done for each program. The Capital Equipment budget also comes from HQ at the beginning of the FY. CRL plans the use of the Capital Equipment funds with staff once the funding allowances are actually received in the current FY. The purchase plan for Capital Equipment is updated throughout the FY until all funds are expended. Budget records are maintained by the CRL Deputy Director.

5.5. Contracts and Grants

5.5.1. Service contracts and grants

5.5.1.1. Analytical services

The CRL does not procure or assess analytical services through the U.S. EPA Contract Laboratory Program or any other contract mechanism. CRL does not subcontract work to any other laboratory. Refer to Section 3.10 for additional information about CRL relationship with the ESAT contract.

Although CRL neither contracts nor subcontracts work, the following 2 scenarios exist. 1) Specific work arrangements as well as emergency and/or disaster type of situations do impact CRL. Refer to QMP Sample Planning (Subsections: 8.2.3, ESAT and 8.2.4, Non-Routine Work) for more details. 2) CRL serves as an on-site operator of an ORD contract. The COR for the ORD contractor is Larry Zintek. The Contractor is Pegasus, owned by ORD-Cincinnati. There are 2 SEEs, one working in the admin area supporting QA and Data Management, and the other working in the Inorganic group as a chemist. Francis Awanya is the SEE COR. The SEEs are arranged by a Regional grant/agreement with NAPCA. CRL buys into this agreement. All CORs are required to take the appropriate initial and annual refresher training to maintain COR status.

Glassware and laundry services for CRL are on a contract procured through the regional contract office.

5.5.1.2. Administrative services

CRL has one SEE enrollee who performs administrative support functions.

5.5.1.3. Vendor support services

Service contracts are requested through a purchase requisition and negotiated by a procurement officer in another office of RMD. The CRL maintains service contracts for its LIMS with Promium, Qualtrax (for QA management system), ELPRO (for remote temperature monitoring system), TechLaw for glassware and laundry services, Progressive Industries, Inc. (for gasses), REMI (for Agilent, Tekmar, and Thermo instruments), other analytical instruments with PTS, and PerkinElmer, and others. The PR requestor (not necessarily always the originator of the PR) is responsible for tracking & renewing the contract through the acquisition process. The CRL Sample Custodian serves as a TOCOR for the database administration support Task of the Region 5 IT contract.

5.5.2. Office contracts

Office supply contracts are negotiated by the General Services Administration (GSA), another agency of the US government. The laboratory facilities, renovations and repairs are managed by GSA in coordination with the Region 5 Facilities Branch of RMD.

5.6. Evaluation of Suppliers

5.6.1. FAR

The U.S. EPA is required to adhere to competition requirements as described in Federal Acquisition Regulation (FAR) Part 6 and does not perform supplier (of services, consumables, supplies, etc.) evaluations.

5.6.2. ISO 17025, 17043 or ISO Guide 34

Policy 011-05: All vendors to CRL providing standard reference materials, especially when used to calibrate instruments, must hold an ISO 17025 and/or ISO Guide 34 accreditation and list the purchase request item under their scope of accreditation.

In the same way PT providers must hold an ISO 17043 accreditation and the purchase item listed under their scope. CRL does not calibrate reference standards.

- ISO 17025 deems technical competence
- ISO Guide 034 deems competence of reference materials producers
- ISO 17043 is the general requirements for proficiency testing

6. Documents and Records

6.1. Definitions

Records (or document) include all books, papers, maps, photographs, logbooks, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value in them. (Taken from 44 U.S.C. Chapter 33, Sec. 3301). All documents are records.

QA documents are automatically published in Qualtrax upon last approval. Once published, the document becomes effective. For the details, including grace periods, concerning the effective dates of policies and procedures contained in these documents, refer to section 2.3.5.

6.2. Master List

The CRL's Qualtrax accounts for the laboratory's document master list. Internal and some external documents are controlled by virtue of Qualtrax updates and maintenance. External documents are also controlled by assuring all staff members use the QA-WI013 designated and reliable website. These website links are placed in Qualtrax (Favorites tab) by the CRL QA Coordinator for easy accessibility. Qualtrax master list function is easily accessible in the system under the Report module. For the master list procedure in Qualtrax use the system's advanced search index and enter "master list."

6.3. Version Control

Policy 012: All QA documents shall be controlled following the provided stipulations.

6.3.1. Security and Control

6.3.1.1. Internal to CRL

CRL procedures prevent any document versions, in whole or in part, from unauthorized use by storing them in Qualtrax where majority of the QA documents reside. Most documents in Qualtrax are only viewable in PDF and the ones available in Word (some outputs) are still considered secure due to Qultrax functionality features. All of Qualtrax documents are created using a controlled feature. In order to amend any document in Qualtrax it must be checked out for tracking purposes and requires approval to be published (effective). Once published the header is automatically updated to reflect its new version number and published date and time. See section 2.3.4 for additional software information details. The CRL QA Coordinator controls all user rights in Qualtrax.

6.3.1.2. Internal to EPA

For EPA clients, the QMP and SOPs (including "pen&inks" deviation documents; see section 6.3.4) are made available on the agency's intranet under the divisions section (RMD/CRL). The intranet has limited read rights to all users except those designated to upkeep the website.

6.3.2. Documents Maintenance

6.3.2.1. Internal to CRL

The CRL QA Coordinator maintains Qualtrax with the current versions of documents. A few spreadsheets contain historical information for tracking purposes but are updated regularly. Electronic editable (Word) files

are made available by Qualtrax to requesting personnel for the use of updating the document (e.g. SOP revision).

All documents become effective once published (upon last approval) in Qualtrax. Once documents with multiple versions such as SOPs become effective, its predecessor version is automatically retired by removing it from the view (Qualtrax Document tree) of all users, except system administrators. All retired documents are only visible and available to system administrators. As of July 2014, documents utilizing Qualtrax' header/footer templates (SOPs, WI, etc.) will include document status (edit, approved, effective, and retired) information in the header. Retired documents can only be attained by making a request to the QA Coordinator who will ensure the file status accurately reflects its retired status. If the retired document does not contain a Qualtrax header file status or the header is not functioning correctly, the QA Coordinator will ensure the document contains a visible watermark to reflect the document's retired status. All QA documents, follow a very similar processing procedure (to that of SOPs) once they are in Qualtrax. For detailed SOP procedures including retiring document information, refer to SOP GEN006.

Requests to view or retire (archive) a Qualtrax document, such as an SOP, are made individually to the CRL QA Coordinator.

6.3.2.2. Internal to EPA (Intranet)

EPA's intranet is updated automatically through a document replication feature in Qualtrax. It automatically replicates designated documents from Qualtrax to the intranet once a week (Friday night). Document replications are currently in place for all CRL effective SOPs, Pen & Inks, and the QMP.

6.3.3. Document Unique Identifiers

Policy 012-01: All QA documents shall contain a unique identification.

Each QA document contains a unique identified number with a published (effective) date, page numbers, and editor/submitter information. Qualtrax automatically generates a unique identifier number for each one of its module products (Documents including each version, workflows including attachments, tests, etc.). Qualtrax Workflows, Document properties and header/footer template provide the following information. For customized SOP and WI document number/name convention, see section 9.3.

- document number
- page numbers (Document header/footer template)
- editor (Documents property) / initiator (Workflow)
- published (Documents) / approved (Workflow) dates
- document status
- the name of the second reviewer and stamped with date upon official sign-off (no header/footer)
- approvers names and stamped with date upon official sign-off (no headers/footer)

6.3.4. Document Changes

QA documents undergo changes when being temporarily (typically SOP deviations) or permanently revised. This section outlines controls over such version and document changes.

Most QA documents are revised for permanent changes during their scheduled review cycle. For QA document review details, refer to section 6.10. Intermittent revisions also occur for various reason most of which concern corrective actions. If time is not available to revise the pertinent QA document, a Pen&ink or New Policy form (CRL Form 001 or 002) must be completed to adhere to the policy described directly below. "Pen&ink" is a common term used throughout this QMP to define a procedure for documenting a one-time or

continuous deviation (policy or procedure) in a Quality Assurance (QA) document. Typically, this applies to SOPs.

Policy 012-02-01: All planned QA policy or procedures deviations shall be documented and approved by management and/or clients prior to carrying out the needed change.

A planned deviation refers to a change in an established QA policy or procedural document deviation that is within the control of the laboratory. This especially applies to an SOP deviations related to analytical work (including test results) aspects. When a method SOP is not followed as written, and provided the change is within analyst or CRL control, a pen&ink change applies. For pen&ink procedures, refer to QA-WI001.

Policy 012-02-02: Amendments to original reported data shall clearly explain the changes made and identify the report it is replacing.

If changes are required for an analytical data reports, the revised report will be clearly marked as a supplemental report in the case narrative going out and elsewhere as needed. Should an entire report need to be replaced with modified results, the new report will contain a statement in the case narrative that this is a replacement of the previous report and give the identification found in the lower right hand corner of the previous LIMS report as unique identification. These type of changes normally address a CA and should also be documented in the case narrative. Alternatively, complete a CA narrative, CRL Form009, and submit it with the revised data if any. All amended case narratives shall go through re-approval by DD.

Policy 012-03: Appropriate staff members shall be properly notified, and when possible a summary of the changes made provided, when QA document (such as the QMP, SOPs, WIs, or pen&inks) changes are approved and published.

At CRL this type of notification is routinely done through a publication notification and/or a New Document Version Record (NDVR) test in Qualtrax. Publication notification may be sufficient is some cases, such a pen&ink change which summarized the document's deviation. In this case, the notification subsection of the file's (pen&ink) properties should naturally include the appropriate and active users. The NDVR test is automatically sent to affected staff (users of the document) members when a revised document is published. A NDVR certifies that the appropriate staff members are aware of the new official CRL document and/or the changes made. Document editors should ensure a NDVR is generated for their published document. If it is not, contact a system administrator to generate it. Some QA document changes, such as minor schedule details for PTs, SOPs, and supporting equipment may not always apply depending on the nature of the change. New documents do not require a NDVR because the publication notification is sufficient for this purpose.

6.3.5. New QA documents

All new CRL QA documents must be included in the CRL Qualtrax system. Contact the QA Coordinator to establish the file locations and document list approvers (including notifications).

6.4. Technical and Quality Records

6.4.1. Original observations and official documents

In order to go substantially paperless, the EPA Region 5 Records Liaison recommends electronic storage systems (including software companies) be compliant to the Department of Defense (DoD) 5015.02 standard (STD) or equivalent, especially as it applies to technical records. This recommendation is put in place at CRL for all QA documents until there are agency-wide guidance and/or requirements concerning electronic storage systems including maintenance. The CRL system for QA documents meets the equivalent DoD standard through the Qualtrax software system in combinations with internal policies and procedures. Therefore, CRL is operating under paperless procedures for all QA documents only. QA electronic files in Qualtrax are

considered the original documents and are maintained according to the system functionality. For more details, refer to the Qualtrax, section 2.3.4.

Starting with the publication of QMP version 6, the CRL's system for technical data records will become as paperless as possible. Therefore, a paperless data package procedure will be implemented into the CRL following SOP GEN032. Once this procedure is in place, the electronic files generated to support and produce analytical data results are considered the original observations and official records. Note: Electronic data packages do not apply to any work categorized under CRL's criminal investigation samples (CIS). The official records for that type of work are the hard copy files. For additional information concerning data packages and final reports, refer to QMP Section 6.11. All analytical data hard copies are stored by the CRL Data Coordinator.

For additional and detailed information regarding data management at CRL, refer to SOP GEN018.

6.4.2. Technical data records

6.4.2.1. Completeness of Technical Documents

Policy 013-03: Records shall include sufficient and legible information so as to retain and allow the reconstruction of all reported analyses.

Sufficient analytical records must be retained in order to perform an audit trail for the LIMS WO to cover its defined period (from the LIMS WO creation date till the day the data was transmitted). For example: Records of analyses leading to reported dilutions and/or data containing failing QC (to demonstrate troubleshooting attempts to resolve the issue) must be retained along with the reported results.

For electronic records that are scanned, ensure the final copy is legible prior to discarding the original documentation.

Policy 013-04: Gaps in sequences or other indication of discarded analyses shall be documented with an explanation of why the analysis was aborted or entirely discarded.

For additional details supporting these policies, refer to section 9.6.4.

6.4.2.2. Electronic Analysis Data Storage

Policy 013-05: All final analytical results shall be entered into the CRL LIMS as the official electronic storage and locked as soon as possible.

Such electronic data is locked in LIMS as soon as possible in order to start an automatic audit trail.

Policy 013-06: Instrument electronic data shall be archived on the CRL secure R5 CRL LAN "I" drive (\\204.46.201.26\Root Share\R5CRL) as soon as possible and according to each group's data verification or upload SOP which includes the group's naming convention.

Analysts are required to back up data including instrument results (with option to process supporting data files) on a daily basis when analyzing samples. Backing up data is routinely done per analysis after the analysis has ended. Instrument results should be backed up with other supporting electronic files needed to interpret the results. If instrument results are not available electronically, then back up any spreadsheets or other electronic files providing such information. Electronic data deliverables, EDDs, should be stored with the electronic instrument data.

Note: The CRL uses a share drive with limited user rights called the "I drive" as a working folder for all of the laboratory's analytical data and it should not be confused with data management systems used to archive official electronic data package records.

6.4.2.3. Data Management

Data management at CRL is described by CRL SOP GEN018. This SOP lists or details all of the activities required at CRL to correctly and completely standardize control of the process of data flow from sample receipt to archival. Each analysis can be reconstructed from the information in the files. For the procedure details concerning the activities required to correctly and completely control the analytical data record flow from receipt (by the CRL Data Coordinator), including transmittal (to client), to archival, and record retention schedules information, refer to CRL SOP GEN018.

Policy 013-02: All official records (electronic or hard copy) must follow EPA records schedule and procedures according to SOP GEN018.

All technical data collected or produced by computers are managed as specified by Agency's IRM policies, directives, standards and guidance documents. This ensures consistent definition of data and facilitates cross-media use of data.

6.4.2.4. Custody of Documents

All LIMS final analytical reports and supporting data such as original instrument data, bench sheets, calculation spreadsheets, summary reports, and original custody forms are maintained under custody by the CRL Data Coordinator.

6.4.3. Quality documents

6.4.3.1. Records and maintenance

Quality records including, but not limited to, reports from internal and external system audits, annual management reviews, analyst DOC certificates, MDL/RL instrument capability, SOPs, QMP, WIs, approved Pen&Inks, and PT records are all filed in the CRL Qualtrax and maintained by the CRL QA Coordinator. Note: QAPPs and completed Analytical Request Forms are stored in the G drive and maintained by the Sample Coordinator. Quality records will be stored for ten (10) years according EPA record schedule 185 (item b), currently being superseded by the new combined records schedule 1035.

6.4.3.2. Qualtrax

In order to "go paperless" the electronic file is considered the original file and must follow directive for the agency Records department. According to the record's department an original document must have appropriate storage (the system must be around for the duration of the record's retention schedule) and record destruction procedures. Qualtrax meets EPA's storage requirements. CRL uses the Department of Defense (DoD) standard 5015.02 as a mechanism to meet electronic archive requirement for records until it produces its own agency (EPA) standard. There are other mechanisms available and the agency is not required to use the DoD standard. In order to meet agency electronic archives for records as well as Environmental Management System (EMS) initiatives (to save paper), CRL will go paperless when using Qualtrax in combination with internally documented procedures for deleting electronic quality data files, QA-WI014. The stated work instruction addresses appropriate retention schedules, litigation holds, and approvals for a record's destruction. Unless printing is a necessity to support technical data, quality assurance documents will not be printed.

A summary of QA document locations are listed below. For Qualtrax software information, refer to section 2.3.4 (Qualtrax software).

- Documents (module) group folders: SOPs, pen&inks, control charts, and spreadsheets all.
- Documents Quality Assurance: Various QA related documents within folders, for example…
  - Accreditation certificate and scope
  - Forms, Checklists, GEN SOPs, References
  - PT: multiple records and schedules
  - CRL QA Coordinator: Audit records, various QA tracking documents
- Documents Work Instruction folder: Various WIs
- Workflows: CAR, Case Narratives, DOC, NCR, PA, PT, Supporting Equipment

6.4.3.3. Share Drive

Completed QAPP and analytical request form records location: G:\CRL Sample Coordinator\QAPPs

6.5. Chain of Custody (COC)

The COC pertains to the ownership (or who is in custody of) specific samples stated in the document. All samples accepted at CRL require a COC to be relinquished to the laboratory upon receipt. For procedural instructions concerning the COC, refer to CRL SOP GEN013.

6.6. Sample Tags

Policy 013-07: Sample tags must always follow their respective work order containers.

All containers, including empty ones, must be returned to the CRL Sample Custodian and back into sample control with sample tags. An exception is for reusable air canisters and containers; then only the tags are returned to the CRL Sample Custodian. For additional procedural instruction concerning sample tags, refer to QA-WI002 (internal clients) or SOP GEN013 (external clients).

6.7. Logbooks and Manuals

Policy 014: All data logbooks and manuals shall follow the stipulations provided below.

6.7.1. Data Logbooks

Data logbooks are used and maintained by multiple or individual staff members for the purposes of documenting original observations.

All data logbooks must include the date and the initials of the analyst making the documented observations per entry. Logbooks must also be paginated (see GEN026 for effective date) and entries must be made in real time, once the action occurs. If instrument print-outs are attached, it should be done as soon as possible to keep entry dates in order as much as possible. Once data logbooks (any and all) are no longer in use, they are submitted to the CRL QA Coordinator for secure storage and archive.

Data logbook entries used for the preparation of calibration standards and samples are photo-copied and submitted with pertinent final data packages. In the case where standard or sample preparation is recorded in LIMS live, there will be no hard copy print-outs to include in the data package. For example, the analyst shall provide a data package hard copy for the balance logbook entry when verifying the balance for soil samples analysis or preparing a calibration stock standard. Data logbook entries for the preparation of reagents do not apply to this procedure (mandatory photo copies in the data package) since this information is unlikely to affect the quantitative results of samples. Nevertheless, this information is entered into LIMS and the logbooks are maintained in the laboratory for tracking and preparation accuracy confirmation purposes.

For logbook identification and other procedures, refer to GEN026 section 6.6.2 (Logbooks).

6.7.2. Instrument Logbooks and Manuals

Instrument logbooks and manuals shall be up-to-date and stored near the relevant instrument.
SOP primary analysts are responsible for assuring updated equipment instructions (use and maintenance) are available in an easily and readily retrieval location near the instrument or as documented in the relevant SOP.

6.8. Work product peer review

6.8.1. U.S. EPA Science and Technology Policy and More

The CRL will adhere to the U.S. EPA Science and Technology Policy Council, *Peer Review Handbook*, 4rd Edition, October 2015 EPA/100/B-15/001, or subsequent editions, as available, for the peer review of all applicable work products. Each time CRL undertakes the development of a new work product as defined below, the initiator of the work product and the appropriate manager, in consultation with the Region 5 Peer Review Coordinator as needed will determine whether the work product will potentially need peer review. If peer review is necessary, the appropriate review process will be followed.

The CRL will adhere to The U.S. EPA's Science Policy Council's (SPC) Forum on Environmental Measurement's (FEM) Agency Policy Directives on Ensuring the Validity of Agency Methods; Methods Validation and Peer Review Guidelines. CRL will adhere to these policies for all applicable methods prepared by the CRL for: (1) publication for general use as an Agency method; (2) publication as regulations; or (3) incorporation by reference in Agency regulations. These methods and techniques can be found under http://www.epa.gov/fem/agency_methods.htm.

Finally, the CRL will adhere to the 1) Information Quality Guidelines, 2) Frequently Asked Questions About Publication Agreements, and 3) Ethics Regulations, and Writing for Publication when publishing any materials publically. Please contact Regional Judicial Officer if you have questions about ethics or documents 2 and 3. Disclaimers can be found here http://intranet.ord.epa.gov/p2/sites/default/files/media/NCCT/appendix_d-disclaimers.pdf .

6.8.2. Analytical Methods and ATPs

The CRL analytical methodologies are documented in SOPs. These procedures are based on analytical reference methods. These methods exist in peer-reviewed sources from

- EPA.
- ASTM.
- Standard Methods of Analysis of Water and Wastewater.
- Peer-reviewed scientific journals.

SOPs are used to generate data. The data may be used to support decisions of Programs or to support their policy agendas. The Program, not CRL, has the responsibility to assess the need for peer review of any report or document with the data.

Peer review may be appropriate for an "Alternate Test Procedure" (ATP) for analytical methods under the Clean Water Act (CWA) and/or the Safe Drinking Water Act (SDWA). A modified regulatory method might become an ATP. To attain ATP status, the method must meet rigorous, written, statistical criteria and follow clear procedures. These procedures include inter-laboratory studies and the use of an outside reference laboratory. The extent of an ATP study depends upon how general the method application is intended to be: national, regional or local.

6.8.3. Technical Papers, Abstracts, Posters, and Presentations

CRL staff may try to publish a paper in a scientific journal. In that case, a peer-reviewed journal would be used and its process would suffice as the peer review. Any external technical paper, abstract, poster, and/or presentation is reviewed and approved by the laboratory Director and/or Deputy Director before it goes out.

There is no product review for Peer Reviewed Documents, submitting articles for publication to journals, or for many other kinds of written or multimedia materials. You must consult with one of EPA Region 5's Print and Multimedia Product Review Officers before issuing print and/or multimedia materials on behalf of EPA for external audiences. There is no need for a Product Review Consultation for submitting articles for publication to journals or for many other kinds of written or multimedia materials. For a complete list of the product review officers for print and multimedia material, see http://www2.epa.gov/product-review/print-and-multimedia-product-review-officers .

6.9. Data verification – For data verification procedure and documentation, refer to Subsection 9.7.

6.10. QA Documents Review

Policy 015: All QA documents shall be reviewed on a regular basis following the stipulations provided below.

6.10.1. General Requirements

QA documents are approved by the parties who reviewed the documents. For a description of the specific reviewers/approvers of these documents, refer to the pertinent subsections (6.10.2-6.10.7) below. The people who review and approve stated documents shall perform the review with access to the original document with or without the Word track changes, known as the redline copy (or equivalent). Redline copies are submitted whenever possible to highlight modifications. Whenever Word track changes are not possible, modifications to the original document may be manually highlighted, initial and dated. Word Access to these documents allow for proper background information to be considered during the review process and are considered minimum requirements. During the review procedure any comments and/or concerns with the document are submitted to the editor and should be addressed prior to routing for approval. Confirmation that reviewer comment(s) have been addressed is done by the pertinent reviewer in the Qualtrax Document approval step.

After CRL Documents are approved, a NDVR record is produced to acknowledge staff document change awareness. Refer to the Version Control subsection 6.3.4 of this document for more details.

6.10.2. Lab-Wide Documents

Standard Practice 001: When a lab-wide policy, procedure, or output is created or revised, the rough draft document undergoes a staff review and comment period to which consideration is made before the CRL QA Coordinator submits the final draft to management for approval. When only minor editorial, formatting, and/or document section relocation (from one QA document to another) is made, this process is routinely bypassed.

Procedure: The lab-wide (not group section SOPs) QA documents are posted in the Outlook share drive (the "One Drive") by the CRL QA Coordinator who also notifies appropriate staff members of the document draft open review and comment period. Staff members may submit document review comments to group representatives who have editing (tracked changes and comments) rights to the file. Note: Although tracked changes are allowed by those with edit rights, statement deletions are not allowed. Replacement of some word choices or grammatical corrections are welcomed, but not the removal of a sentence(s). Instead, a comment to

recommend removal of a statement is acceptable. Review and comment period due dates are generally based on the following guide but the CRL Director(s) may assign the final dates.

Document Type	Ave. # of pages	Due Date Time Frame
Outputs (forms, etc.)	2	5 working days
New Policies (via CRLForm002)	2-5	5 working days
Work Instructions	5	5-7 working days
SOPs	40	15 working days
QMP – Interim (QMP section(s))	115	15 working days
QMP – Annual (entire QMP)	115	30 working days

6.10.3. SOPs

All SOPs, except those accredited for drinking water, are reviewed at least once every two (2) years according to a schedule. Any SOP listed under the scope of accreditation for drinking water must be formally reviewed annually to meet drinking water requirements (MCLADW, 5th edition, Chapter Ill, 11.3). Every SOP goes through a systematic review and approval chain: Editor, Second Reviewer, CRL QA Coordinator, CRL Deputy Director and/or CRL Director. Refer to section 9.4.4 for additional SOP Revisions details and section 9.4.5 for SOP Routing, Approval, Tracking details. Refer to section 9.4 in general for all other Standard Operating Procedures (SOPs).

6.10.4. Work Instructions

QA-WIs are typically reviewed at least once every two years or sooner as needed. The Qualtrax document expiration date records and schedules the 2-year revision when it is due. Revised QA-WIs and forms are reviewed by the Management Assistant (administrative review) and Analytical Staff Members (technical and policy changes) whenever possible. Then the document(s) is reviewed and approved by management (CRL Director and/or CRL Deputy Director). Routinely the CRL QA Coordinator edits WIs, but staff members are allowed as long as the CRL QA Coordinator reviews the document. General or group specific work instructions are reviewed and approved by the editor and qualified second reviewer. Unless lab-wide instructions are included in the work instruction, the CRL QA Coordinator, Deputy Director and/or Director do not need to approve.

6.10.5. Spreadsheets

Whenever possible spreadsheets used for calculation of analytical results or collecting data must be reviewed and approved by a second reviewer prior to use. In the absence of attaining formal spreadsheet approval, the primary analyst and second reviewer of the data are responsible for ensuring all calculations are accurate keeping in mind multiple and repeated fields. For creating a spreadsheet document and designating approval parties in Qualtrax, refer to QA-WI015. General and group specific spreadsheets are reviewed and approved as needed. If the revised spreadsheet/calculation sheet applies to a lab-wide used instrument (such as LIMS or balance software), the CRL QA Coordinator and/or Deputy Director must approve. Otherwise, a second reviewer is the final approval.

6.10.6. QMP – Refer to section 2.2 for QMP Review and Modifications procedural details.

6.10.7. Client Documents

The CRL Sample Coordinator reviews and maintains all general requirements documents submitted to CRL. Refer to subsections 3.7.5.1 - 3.7.5.8 for CRL Sample Coordinator responsibilities. Electronic records are stored in the G drive and/or LIMS and for the most part are not printed (except for analytical request forms) since the clients hold the original files. Appropriate client document selections, such as the DQOs of a QAPP and/or non-conforming deviations of routine procedures, are printed and included in the CRL data package.

Beginning with the publication of QMP v4, The CRL Sample Coordinator (or management designated party) will attest to the accuracy of all LIMS work orders (WOs) by setting their LIMS status to 'available.' The Sample Custodian must ensure WOs or at a minimum specific analysis sample(s) within a WO are verified as indicated by its 'available' status in LIMS before checking samples out to analysts. Note: For PT clients, the CRL QA Coordinator verifies the WO.

6.11. Data Packages

Policy 030: Data reports and packages generated at CRL shall follow the protocol described below.

In order to be compliant with our accreditation standards, all reports and data package compilation must follow GEN032. This SOP in combination with QA-WI006 (case narratives) is designed to meet the majority of the requirements stated under ISO 17025 section 5.10 (Reporting the results). Instructions for the compilation of group specific data package are also included in GEN032. Note: Due to the fact that the CRL's clients are internal, some results may be reported in a simplified way and any information listed in ISO sections 5.10.2 to 5.10.4 which is not reported shall be readily available in the laboratory.

All data report formats regardless of electronic, hardcopy or delivery option (fax, interagency mail, e-mail, etc.) and including amended reports must follow the requirements stated in GEN032. All analysts are required to use a LIMS report for final result reporting.

Per ANAB policy, the CRL is required to use an accreditation body logo on analytical reports with SOPs listed under our Scope of Accreditation. The logo illustrates the laboratory's accreditation to ISO 17025 for SOPs (per matrix) listed under the accreditation scope. The current scope of accreditation can be found in Qualtrax under the Quality Assurance folder. CRL second reviewers verify proper use of the logo on all client reports.

CID project cases require different needs. For CID client report requirements, refer to SOP GEN007, Data Management section. Note: CID work and data archival must not be combined with any other project or work order.

Data validation and quality assessment is the client's responsibility. CRL data packages are designed to support data verification. Packages provide adequate instrument printouts, summarized QC reports and a narrative highlighting any problems, observations or other significant findings about the samples or analysis. CRL provides qualification codes on its data to facilitate data validation and quality assessment.

7. Information Technology

Policy 016: Instrument software and hardware used to generate or store electronic sample analysis data shall adhere to the following stipulations.

7.1. Retention

Policy 016-01: Instrument software used to generate, read or store electronic analysis files shall remain available to access the record for the retention period of the record.

This should allow enough time for any questions about the data processing to be posed. Once an instrument software is no longer used, submit it to the CRL Deputy Director who will store it in a secure area. Record Schedules can be found at http://www.epa.gov/records/policy/schedule/index.htm .

7.2. Verification

CRL computer hardware is kept up-to-date with documented operating manuals and instrument maintenance contracts. CRL keeps written, hardbound maintenance logbooks next to each instrument. Software will be purchased with full licenses for all hardware units using the software. All instrument software is standard commercial software backed by the instrument company.

Policy 016-02: Analytical instrument software shall be tested and verified by the vendor before installation so that this laboratory does not need to do a formal verification of such software.

Software verification and/or validation, along with any installation qualification check documentation should be provided and stored near the pertinent instrument or in that logbook. All computer hardware and software is kept up to date to meet all applicable Agency standards.

With computers playing a critical and important role in the daily operations of the CRL, it is essential that the LIMS, LAN and data systems be adequately and appropriately documented. The computer contractors currently maintain and document the adequacy and integrity of CRL data operations. They assist CRL by assuring that the hardware and software systems installed on CRL instruments and workstations are technically supported.

The CRL complies with the computer hardware and software requirements of the region documented in the Region 5 QMP. Refer to the USEPA OEI Chief Information Officer (CIO) Policies Procedures Standards and Guidance intranet link: http://intranet.epa.gov/oei/imitpolicy/policies.htm . CRL computer systems are supported by an onsite contractor, overseen by staff in the Information Management Branch (IMB). To ensure the effective and efficient use of the regional Automated Data Processing systems, including hardware and software system design, development, implementation and maintenance, the CRL follows the EPA Information Resource Management (IRM) policies, directives, standards and guidance documents. Any questions regarding IRM should be referred to IMB.

CRL instruments are always within control, even when used by contractor staff. When contractor staff uses CRL equipment, that instrumentation is not considered to be outside of the laboratory's control because contractors are required to use CRL SOPs, which comply to ISO 17025 standards. That being said, and per CRL SOP instructions, CRL analysts still check the instruments to ensure they are performing accurately and meeting ISO standards by running QC sample analysis prior to field sample analysis.

7.3. LAN

The CRL Local Area Network (LAN) is used to store and back-up data associated with LIMS, Qualtrax, and two share drives ("I" and "G"). Although the agency is moving towards share point sites, CRL utilizes such sites whenever possible but remains active users of the LAN due to software interferences with the internet and/or intranet and therefore lack of internet accessibility in the testing rooms where the analytical instruments are located. For confidentiality concerns regarding share drives/sites, see policy 008-04.

All LAN issues must be addressed through contacting the computer help desk at 3 - HELP (34357). The LAN is maintained by the LAN Administrator contractor. The LAN is primarily used for data communication and reporting.
The CRL LAN is backed up according to the following schedule. The data is backed up to Magnetic tapes, and the tapes get shipped off weekly to an offsite storage facility.

- R5RLIMS_Full (Server backup - runs every Friday at 11:00 pm.)
- R5LIMS_DB_Full (Database backup - runs Monday, Tuesday, Wednesday, Thursday and Friday at 6:00 pm.)
- R5CHEM-WIN-Full (Server backup - run every Sunday at 4:30 pm.)
- R5CRL- Vol1, Vol2, Vol3 and Vol4-WIN-Full (Network drives backup - run every Friday at 5:00 pm.)
- R5CRL-CHEM-WIN-Differental (Server/Network drives backup - run every Monday, Tuesday, Wednesday and Thursday at 5:00 pm.)

7.4. Sharepoint site

CRL uses its share point site to share general laboratory information and upon client request, copies of full technical data packages. Each folder in the share point site has limited user rights accordingly in order to safeguard the data. The records shared are only copies. The official records are archived according to GEN018. For confidentiality concerns regarding share drives/sites, see policy 008-04. https://usepa.sharepoint.com/sites/R5/CRL/SitePages/Home.aspx

7.5. LIMS

The CRL Laboratory Information Management System (LIMS) complies with the Agency's IRM policies, directives, standards and guidance documents. This system operates on an agency standard database, Oracle. The software was verified by the procuring consultant before installation. A maintenance agreement with the current vendor includes upgrades and improvements to the software so that the system remains current.

LIMS security is maintained with user identifications and passwords for access. Various users are granted privileges for access and modification suitable to their work needs.

Policy 016-03: LIMS user rights shall only be used for to meet their job description.

To view a list of set user rights in LIMS, refer to Qualtrax/Documents/Quality Assurance/Spreadsheets/ LIMS set user rights.xlsm. On occasion and only with management consent users with extra rights may help troubleshoot some functions, pilot a new software version, or correct some information fields. Client sample and project information shall only be modified by an appropriate party or designated individual (e.g. CRL Sample Custodian or CRL Sample Coordinator) provided the reasons for such changes are traceable. Users with additional rights shall not edit client sample and project information without the consent and guidance of management. The LIMS application has many security features that prevent changing data in unapproved ways. The Oracle database can be accessed directly only by the Oracle administrator, a contractor.

7.6. Functionality

Data collection, analysis, processing, and storage are primarily handled by dedicated instrument computer systems found throughout the laboratory. These systems are connected to various types of analytical instrumentation. Both the computer systems and analytical system are maintained in a proper environment throughout the laboratory. Analytical instruments are maintained according to vendor requirements and recommendations. Computers are maintained by the IMB department. All data collected using CRL instruments and computers are in accordance with CRL analytical SOP requirements. Changes to the computer systems are tested by the analyst through the analysis of samples according to the pertinent CRL SOP. All computer systems are connected with the Laboratory Information Management System (LIMS).

The CRL Sample Custodian is the technical contact for the computer contract in the laboratory. The CRL Sample Custodian is also the data administrator for the LIMS.

7.7. Security

The instrument equipment at the CRL, including hardware and software, are secured from adjustments which would cause invalid results by adhering to a CRL internal policies, including;

7.7.1. Securing the physical facility to only allow CRL employees, ESAT contractors, Interns, and GSA access throughout the laboratory via lock door combinations and ID card scan to enter each room.
7.7.2. Training for all employees to properly operate equipment and software.
7.7.3. Practically configuring software to analysts from overwriting existing records (e.g. raw data).

7.7.4. Applying password protection and timed, locked screen savers to pop up due to inactivity on PCs attached to equipment. - Whenever data acquisition allows.
7.7.5. Locking calculation fields on spread sheets, whenever possible and reasonable.
7.7.6. Archiving data files on the LAN
7.7.7. Backing up the LAN regularly. Refer to LAN subsection 7.3 for more details.
7.7.8. Participating in an annual IT awareness training.

7.8. Qualtrax

The data generated by Qualtrax is stored on an EPA R5 CRL server which is backed up weekly. The R5CRLOra server where the Oracle database is located is also backed up weekly during the night. All servers are backed up to tape. The Qualtrax Oracle database is backed up daily during the night.

7.9. Internet

Policy 016-04: For security purposes, all instrument computers shall have limited internet access.

Instrument computers are allowed to have internet access limited to allowing vendor patch repairs and/or software upgrades. Limited internet access undergoes approval by management and IMB during its purchasing and/or installation procedure. This policy does not apply to computers located in the administrative area of the laboratory as those computers have broader internet access.

8. Sample Planning and Work

8.1. Review of New Work and Capacity

8.1.1. Sample projections

CRL's planning processes concentrate on meeting the needs of its clients through sample projections. Clients identify the expected number of samples, matrices and analytes, which they expect to submit to CRL for analysis. All sample planning is coordinated through the CRL Sample Coordinator. For client communication, scheduling and sample work discussion including final analysis request procedures, refer to work instruction GEN-WI002.

8.2. Sample Work and Requirements

8.2.1. Routine work

8.2.1.1. General requirements and documentation

For details outlining how analytical work is submitted to the CRL including required documentation, refer to section 2.4. Samples not submitted according to this outline will be rejected. Normal program activities are not considered emergencies and are included in this policy. Failure to plan does not constitute an emergency.

8.2.1.2. Applicability

This policy applies to all chemical, biological, and physical sample analysis and method development that is performed on all environmental sample media, such as, water, soil, sediment, sludge, air, and tissue for CRL's clients, which include EPA Region 5 program offices, state agencies, tribal organizations, and the public.

8.2.1.3. CRL Sample Coordinators

Only the officially designated contact person or alternate in each division or program will interface with the CRL Sample Coordinator for sample projections. This person will be responsible for sample projection updates. Refer to section 3.7.5 for CRL Sample Coordinator responsibilities. Other than the communication stated in this section between CRL Sample Coordinators, refer to section 10.8.2 for client notifications.

8.2.1.4. Chain of Custody – For chain of custody information, refer to section 6.5.

8.2.2. CID

Work request from the CID must follow CRL SOP GEN007. CID work has a separate CRL protocol that incorporates many of the routine work components but can supersede with the requirements in SOP GEN007.

8.2.3. ESAT

For ESAT including TOCOR general information, refer to section 3.10, ESAT. Shared work between ESAT and CRL is limited to using calibrated instruments (sharing instrument calibrations.) and prepared or stock standards and/or reagents. There is to be no sharing or mixing of batches. The following provisions must be met:

- The work does not concern an initial or continuing DOC for the analyst or instrument.
- Communication is made between parties and TOCOR concerning the use of work. The TOCOR should be the official communicator between CRL and ESAT.
- Clear association of who generated which data is documented.
- Traceability is provided by documenting the original work information. This can take many different forms. Examples include but are not limited to the following: A memo to file explanation, a photo copy of the stock standard and/or reagent logbook details, inclusion of the original LIMS ID or preparation details in the current (possibly regenerated) supporting data documentation and respective LIMS system, etc.

8.2.4. Non-routine work

8.2.4.1. MOU

Based on Memorandum of Understanding (MOU), analytical work requests can be referred to any regional laboratory including CRL. Additional details can be found at the following link: http://www.epa.gov/superfund/health/contaminants/radiation/mou.htm . In such a case, the work client most likely becomes the CRL Sample Coordinator from the regional laboratory distributing the work. Emergency type of work is considered non-routine but covered in section 8.2.5, directly below.

8.2.4.2. Preliminary results

Preliminary results will be reported without secondary review, but still undergo the same transmittal procedures as final results. These data are clearly marked as preliminary and subject to change as noted on the LIMS preliminary report format. Changes in the preliminary data should be noted in the final narrative. A complete and reviewed data package is created according to our standard procedures to support the information provided.

8.2.5. Emergency work

8.2.5.1. Background

An emergency is an immediate and time-critical event concerning human health and safety. The CRL Director or CRL Deputy Director acknowledge an emergency situation after discussion with the client and decide on the appropriate action. Shall an incident of national significance occur, Emergency Response

Laboratory Network (ERLN) will be invoked. Additional details can be found at http://www2.epa.gov/emergency-response/environmental-response-laboratory-network.

Emergency support from CRL will follow different quality procedures than our usual samples since human health is concerned. Since these analyses are time critical, a QAPP will not be required. A statement from the client, specifying qualitative or quantitative results, will suffice as the project's DQOs.

CRL operations in support of the remediation and recovery phases following such an event will follow our standard procedures with the following stipulations summarized below.

8.2.5.2. Modified general sample procedures

Emergency samples will be entered into LIMS according to our procedures, but the analysts may start taking aliquots as soon as samples arrive. If the client has specific requests, those will be done first. At the very minimum, there should be a discussion between the CRL and the requestor to determine what analytes/ parameters are needed. If the client still does not know what tests to request, we can begin with multiple parameter tests, such as Volatile Organic Analysis (VOA), Semivolatile Organic Compounds (SVOA), Pesticides and total Metals. Liquid Chromatography Mass Spectrometry (LCMS) will be used to look for toxic compounds found in our developing analytical library. PCBs, Mercury, Cyanide and Hexavalent Chromium will follow. Other tests may be added, if available, depending on circumstances.

8.2.5.3. Modified analytical procedures

CRL's quickest methods of preparation and extraction will be used. No matrix or preparation QC samples will be prepared. If the client requests quantitative results, check standards and blanks will be analyzed with the samples. If the client requests qualitative results, only a blank is required to eliminate false positives. Instruments will be calibrated according to the currently effective SOP for that analysis.

8.3. CRL Workload scheduling

The CRL procedures require that an analytical request form (CRL Form008) be submitted to the CRL Sample Coordinator prior to sampling. With the exception of non-routine work, a request for analysis includes submitting the analytical request form, an approved QAPP or equivalent to CRL. Information provided by this request includes the number of samples, matrix type, analyses, the analytical time frame allowed, proposed date(s) of sample arrival, names and phone numbers for the contact person, project manager and the data recipient, and the GPRA program code for cost tracking. Due date(s) for final reports will be negotiated according to the policies in this management plan. Special arrangements may be made to handle large shipments of samples in a short amount of time. Method development, QA/QC, and special projects are considered analytical work.

8.4. CRL sample handling

Policy 017: CRL client samples shall be handled by following the provided stipulations.

8.4.1. Sample receiving

Policy 017-01: Client samples shall be checked in upon receipt according to CRL SOP GEN013 including, but not limited to, assign a unique sample number to each container.

SOP GEN013 describes all aspects of sample custody and tracking. Following are some stipulations of this policy which are described further in GEN013.

- Sample temperature is determined upon receipt and documented in LIMS.

- Samples are stored in a walk-in chamber cooler which is temperature controlled and locked for security purposes including limited access to the CRL Sample Custodian. Samples are always secured in locked laboratories or a locked sample receiving area.
- Client sample documents are reviewed and cross checked against the CRL sample schedule and preservation table.
- Sample discrepancies and issues upon sample check in are addressed and documented through a control of nonconforming work (section 9.10) procedure. Example: Samples arrive in a condition that does not meet the handling and preservation criteria in the Holding Times, Preservation & Containers table, or without adequate documentation.
- Sample work order review is performed prior to releasing samples into circulation.

Policy 017-02: The analytical data results of samples that are collected in the field the same day they are delivered at the laboratory shall not be qualified based on temperature requirement exceedance.

Samples that are collected in the field the same day of delivery to the CRL may likely not have an opportunity to meet the required preservation temperature because of their quick transit: The ice in the sample coolers may not have enough contact time to cool them to the required temperature. Therefore, the temperature taken upon receipt at CRL is not representative of true preservation procedures and the resulting data should not be qualified based on the temperature requirement exceedance.

8.4.2. Sample IDs

All samples must be logged into the LIMS upon arrival at the laboratory and given unique sample numbers. These sample numbers are used throughout the life of the item for traceability purposes. Extracts and digests use sample identifiers. There should be no confusion regarding the identity of any sample or extract at any time. A final result is entered into LIMS for each analysis and analyte for each unique sample number.

8.4.3. Storage in the laboratory

Policy 017-03: Samples for analysis shall be kept in refrigerators separate from where the standards are stored.

Samples for volatile organic compounds are kept separated from any other samples or organic standards, once they reach the laboratory. If refrigeration is deemed inappropriate or problematic for the sample, other storage may be used so long as the location is documented in the LIMS.

8.4.4. Internal LIMS sample custody

8.4.4.1. LIMS sample check in/out – After the CRL Sample Custodian has finished the initial sample log in procedure, two (2) people must be present whenever samples are checked in or out via LIMS, one to receive the samples and one to relinquish them. Samples must be returned to the CRL Sample Custodian in person. The analyst, CRL Sample Custodian, and samples must be present for check out procedures. For procedure details, refer to SOP GEN013.

8.4.4.2. CID work – For the internal transfer of custody of samples procedure concerning CID samples, refer to SOP GEN007.

8.4.4.3. Transfers within groups – Sample transfers between analysts within a group do not need to be recorded in LIMS, but both parties should agree that custody will change hands before it occurs. When a group member checks out samples they are representing the entire group as well. LIMS documents group and person which checked out the samples.

8.4.4.4. Transfers between groups – When an analyst wants to obtain samples from an analyst in a different group outside their own, the record in LIMS needs to be updated to reflect the new owner before the samples are transferred.

8.4.5. Subsampling

Policy 017-04: Before an aliquot is taken from a soil, solid, or sediment sample for analysis, it shall be mixed well and debris observed to not be part of the sample shall either be retained or removed according to CRL SOP directions.

Any separated liquid should be mixed back into a solid sample unless the client has other instructions. Sticks, rocks, insects, trash and other debris that are not soil are excluded unless requested by the client. Inclusion of debris by client request and/or removal of debris from a sample shall be documented in the case narrative. When unsure about removing debris because it may or may not be part of the sample, always attain client consent before proceeding.

Analytical SOPs give further details about subsampling. Checking pH or Chlorine residual, if necessary, is part of each analytical SOP and is recorded on the appropriate bench sheet in the analytical package.

8.4.6. Field QC sample classification

Field quality control samples will be appropriately prepared for analysis but will not have matrix dependent, analytical quality control samples with them. The field quality control samples will be treated as the same matrix as the samples to the extent that is reasonable. These samples are sometimes in a different matrix from the actual samples. The most common example is a water equipment rinse blank for soil samples.

8.4.7. Retention of physical samples

No samples will be disposed of earlier than 180 days from the date of analysis unless client approves otherwise. Due to limited storage space for samples in a controlled temperature environment, samples are relocated to a room temperature secure storage space. For sample (including extracts, digests, etc.) and sample container disposal protocol, refer to SOP GEN013.

8.5. Health and Safety

Health and safety hold an important place in any laboratory and are priorities for CRL management.

Policy 018: The following health and safety instructions and/or policy stipulations shall be followed at CRL.

8.5.1. Chemical Hygiene Officer and Plan

The CRL Chemical Hygiene Officer (CHO) is a contractor, overseen by a member of the Resource Management Division's Health & Safety Team. The CHO communicates all safety matters to the CRL Director or CRL Deputy Director. Health and safety procedures are documented in each CRL analytical SOP and in the CRL Chemical Hygiene Plan. The Chemical Hygiene Plan will be reviewed and revised each year. The CHO is available for consultation on personal protective equipment. Completely new laboratory procedures are reviewed by the CHO before any laboratory work is conducted to assure that appropriate safety procedures are in place. Analysts should be familiar with the CRL Chemical Hygiene Plan and refer to it when needed.

8.5.2. Communication and Housekeeping

Communication between CRL’s clients and the CRL Sample Coordinator is critical to assure that laboratory employees are not exposed to unknown hazards presented by environmental samples. Information provided to

the CRL Sample Coordinator before sample submission will give the laboratory staff time to prepare appropriate procedures and personal protective equipment necessary.

Conforming to good safety practices and analytical work, the workspace shall be kept clean and neat so that accidents and mistakes are not fostered by work surroundings. The CRL Chemical Hygiene Manual has detailed policies and practices, including waste handling procedures. All work rooms in the laboratory (not administrative area) shall store work materials in an organized fashion so that thermometers, pipettes, glassware, and other instrument or supporting equipment shall have individual, designated areas or drawers that are labeled.

To assist with conforming to good laboratory practices and housekeeping, the CRL CHO performs a monthly laboratory walk-through. The findings of these audits are documented in a report to the Deputy Director via email who then follows up with staff to address issues. All reports should be uploaded and available in Qualtrax (Document tree/Safety folder).

8.5.3. Health & Safety

Two analysts in the laboratory – Analysts are not permitted to work in the laboratory by themselves. At least two (2) people must be present at CRL whenever laboratory work is being done. Phones are provided in every laboratory for emergencies and repair consultations. When weekend work is required, two people will be present at CRL and check on each other at regular intervals. When working in an isolated laboratory, such as an environmental chamber, an analyst should tell others and post a sign in the hall, if possible. Fire wardens should be aware of isolated spots such as environmental chambers and check them in case of a fire.

Visitors – The CRL tour policy requires that all visitors to the analytical laboratories must wear approved safety glasses, follow all safety rules pertaining to the laboratory and be accompanied by at least one CRL staff person at all times.

Medical monitoring – Medical monitoring of analytical staff is mandatory.

8.5.4. Sample acceptance or rejection by CRL

The CRL is equipped to and will only receive and perform analysis on environmental samples that contain known pollutants; samples that are considered to be "Low Hazard" (contain less than 15 percent of a single pollutant in accordance with the U.S. EPA Sampler's Guide Contract Laboratory Program Guidance for Field Samplers OSWER 9200.2-147 October 2014 https://www.epa.gov/clp/contract-laboratory-program-guidance-field-samplers). Samples considered "High Hazard" and contain unknown pollutants or high concentrations or samples containing dioxin will not be accepted.

Samples arriving with prior discussion and notification of high levels for TSCA PCB inspection or enforcement; or RCRA characteristics or for emergency threats to drinking water supplies will be accepted. The following descriptions are examples of samples that must not be shipped to the CRL for analysis, storage or disposal:

- Radioactive samples
- Suspected or detectible levels of Dioxins
- High Hazard samples containing more than 15% of a single pollutant
- Samples with unknown pollutants, drum samples, tank samples
- Chemical warfare agents

8.5.5. Disposal

8.5.5.1. Spent bottles

The proper disposal of bottles is a critical laboratory operation to prevent solvent release to the atmosphere and to minimize exposure to those persons who must handle these bottles. Primary responsibility for implementation of this procedure rests with the analytical staff (AS) and contractor support (CS). For the disposal procedure concerning samples, refer to SOP GEN013. For the disposal procedure of standard, reagents, and solvents, refer to SOP GEN026.

8.5.5.2. Waste

If sample waste accumulation begins to affect the laboratory working space, staff members should contact the CRL Sample Custodian or the CHO. Waste accumulation can create an unsafe environment to staff analysts. The CRL Sample Custodian and the CHO may not always be aware of waste accumulation levels.

9. **Implementation of Work Processes**

9.1. Analyst Routine Performance

Routine performance of analysts with their CRL analytical SOPs is measured against technical and quality requirements set forth in those SOPs. Performance is measured through review of analytical data, analysis of PT samples, and in technical, evidentiary, data and systems audits. Assessments of CRL analysts' performance will be overseen by the CRL QA Coordinator.

9.2. Timely Evaluation of Quality Control Data

CRL policy is to evaluate analytical data and associated quality control in a timely manner. Timely evaluation will allow analysts to re-prepare and/or re-analyze samples before holding times expire. Even timely review may not make unqualified results possible for short holding time parameters.

9.3. Analytical Methods

9.3.1. Current SOPs

Most analytical methods used in the CRL are based on regulatory methods, official guidance, or reviewed published methods in recognized references. Qualtrax (Report module) easily produces a list of all current SOPs. The intranet (Divisions/RMD/CRL) also contains a replicate of all of the CRL's current SOPs. The SOP editor ensures that the most current SOP is being used for annual SOP revision by checking it out of Qualtrax and editing that version.

9.3.2. Alternate test procedures

EPA Alternate test procedure citations will be in the SOP References Section. Methods may be modified from the references to enhance performance. Modifications from a published EPA method will be listed in an appendix in the applicable SOP.

9.3.3. Method appropriateness

During the planning stage of potential work for CRL, data quality objectives (DQOs) are discussed with the client. Project DQOs are included in the project QAPP and Sampling Plan. These documents are consulted in the process of determining whether the methods being planned for use are appropriate. The CRL Sample Coordinator informs the client of the analytical method to be used for a specific project by discussing CRL's analytical capabilities and related project details during the initial request for work. During CRL Sample Coordinator and client conversations, determination of method appropriateness and other related method details (including information on out dated or updated method), issues, questions, or specific requests are discussed. Should a client propose to use an inappropriate or out of date method, the CRL Sample Coordinator shall inform the client.

9.3.4. Before use

Before use, any CRL method must have an approved SOP and documented method validation when appropriate. Research projects may be the only exception to this rule as long as the client provides consent prior to accepting samples at CRL.

9.3.5. Infrequently used methods

For such procedural instructions, refer to QA-WI003 section 2.1, PT Order Determination. During PT ordering season, frequency of SOP use is evaluated in order to determine the continuing method PT participation and possibility for retiring unused ones. An SOP is considered to be inactive if analysis has not been requested for at least two years, and it is not based on a regulatory method. Inactive SOPs will be considered for archiving unless required to remain in use due to special needs (i.e. enforcement or criminal work, etc.). An SOP is retired (archived) when it is inactive, replaced by a newer official version or for other reasons documented in the request to archive.

9.3.6. CRL complete SOP listing

For a complete listing of all (archived, current, in-progress) CRL SOPs, refer to Qualtrax (Quality Assurance folder), run a Qualtrax Report or contact the CRL QA Coordinator.

9.4. Standard Operating Procedures (SOPs) and Work Instructions (WIs)

9.4.1. Naming convention and format

The first 3-6 letters of an SOP normally indicate the SOP purpose. Analytical SOP use CRL group or analytical technology as part of its identification while non-analytical SOPs use the abbreviation GEN indicating general procedures.

- "AIG###" is used for Analytical and Inorganic group SOPs
- "GC###" …for GC group SOPs
- "GEN###" … for general in-house SOPs
- "Metals###" …for Metals group SOPs
- "MS" … for MS group SOPs
- "MoBio" … for Molecular Biology group SOPs
- "OM" … for OM group SOPs

CRL SOPs follow a standard section format for all technical SOPs and shall be followed beginning on the effective date of Gen006: Rev7. Old, established SOPs shall be revised in accordance to the annual SOP revision schedule. For SOP details concerning standard format and other guidelines including, but not limited to creating, reviewing, revising, refer to SOP GEN0006.

Work Instruction naming convention is similar in nature. The first 2-6 letters represent the section to which the WI applies followed by the number. For example,

- "QA-WI###" is used for a QA related WI
- "GEN-WI###" … for a general in-house WI
- "MS-WI###" … for a MS group related WI

9.4.2. Use and locations

9.4.2.1. Use

Policy 012-04: All procedural documents (e.g. SOPs) shall be followed exactly as written.

Analysts must follow official SOPs exactly as written, or data of unknown quality may result. An official SOP is the latest file version in Qualtrax. Staff must use official SOPs, printed out or viewed on-screen for all analyses. The use of Archived SOPs is not permitted without the performance of an IDOC study (See QA-WI002) and obtaining the required approval signatures. Approved SOP deviations are an exception to the requirement that official SOPs be used by analysts exactly as written, but only if the deviations are approved as described in section 9.3.3. Work instructions should also be used as written.

9.4.2.2. File locations

Electronic SOPs are available in Qualtrax, the agency intranet, and temporarily in LIMS until it is determined that sufficient bench work stations in the laboratory have internet access. WIs are also located in Qualtrax but not the intranet or LIMS. Qualtrax is a web-based software which allows users to access SOPs in the entire laboratory so long as there is internet access. To view SOPs, access Qualtrax and go to the appropriate group SOP folder under the Document menu. To view SOPs in the intranet, go to the following link. Intranet link: http://www.r5intra.epa.gov/Div/RMD/CRL/Documents.htm

9.4.3. Deviations

An SOP deviation is a departure from an SOP ideally to accommodate one-time special circumstances. SOP deviations can also apply to routine (referred to as "continuous" in QA-WI001) changes pending SOP modification and have a 45 day turn around to revise affected SOP. Both one-time and routine changes to an SOP are categorized as unintentional or planned deviations in order to determine appropriate policy procedure.

An unintentional deviation refers to a deviation that is not within the control of the analyst or CRL. For example, samples arriving above a regulation required temperature, samples improperly preserved (in the field), client complaint, etc. When an unintentional deviation occurs, control of nonconforming work must be followed. When a deviation is unintentional, the initiation of a nonconformance report (NCR) workflow instance as well as feedback from the Deputy Director is required before continuing work. Refer to QMP Section 9.10 for Control of Nonconforming Work.

When a deviation is planned, as defined in section 6.3.4, a pen&ink procedure must be completed with appropriate approvals and client consent when it affects the data, prior to pursuing the SOP deviation. Stated procedure for a planned deviation is herein referred to as pen&ink. For instructions on how to perform a pen&ink, refer to QA-WI001. SOP planned deviations must be documented (pen&ink document) and approved prior to performing he changed procedure. Failure to perform a planned deviation with an approved pen& ink change shall result in a CA. When unaware if a deviation is unintentional or planned, always consult the CRL QA Coordinator.

Work instructions must also be used as written and similar SOP concept as described above applies. However, because these tasks are routinely broken down to great detail in an electronic fast pace changing era, some minor administrative deviations may temporarily apply. For example, a Qualtrax or LIMS feature for naming a document or sample respectively may change location during a software upgrade. All deviations affecting analytical results shall be documented as described in policy 012-03.

9.4.4. SOP Review and Revisions

Policy 015-01: In order to assure all SOP documents are reviewed and up-to-date according to the latest method reference and SOP GEN006 (SOP for SOPs), the following stipulations shall be followed.

9.4.4.1. Minimum requirements

Refer to the minimum requirements stated under the QA Documents Review section 6.10 of this document.

9.4.4.2. Schedule

All active SOPs are reviewed every two years, except for those listed under the accreditation for drinking water, on their scheduled alternate year regardless of intermittent revisions. A list of SOPs with their respective alternating year for scheduling, can be found in Qualtrax under the QA folder (CRL QA Coordinator/Tracking). SOPs listed under the scope of accreditation for drinking water must be reviewed annually.

9.4.4.3. Reference method updates

All SOP primary analysts (usually the SOP editors) are responsible for keeping up with the latest reference method version and updating changes accordingly (SOP appendix). Method reference updates are released by the daily Federal Register. CRL shall check the daily Federal Register notices pertaining to 40 CFR part 136 for updates.

If a reference method in an EPA regulation has been updated making CRL's SOP obsolete, then the primary analyst for that test method shall revise the SOP (to reflect any changes) as soon as possible, regardless of the SOP revisions schedule). If a CRL method reference is still valid (not obsolete) under the EPA regulation regardless of the latest update, then the reference method is acceptable for continual use.

All SOP deviations from their reference method are to be documented in detail as an appendix, clearly identifying the changes made. A statement shall also be made in the Scope of the SOP making reference to the appendix where all the deviations can be found.

If a change made in the standard method affects the sensitivity of the instrument or method, an IDOC must be repeated to confirm acceptability.

9.4.4.4. Control charts

Editors assigned SOPs under the fixed annual SOP revision schedule, must generate, review, and evaluate QC audit control charts (when applicable) in order to update the SOP QC limits and/or values as appropriate and whenever allowed by the method reference. Second reviewers shall verify the changes made are acceptable. Refer to SOP GEN006 for procedural details.

9.4.4.5. Annual SOP checklist(s)

Annual SOP revisions shall be submitted with a SOP checklist plus any other information appropriate for the review and revision process. The checklist is available in the Qualtrax under Documents/Quality Assurance (checklist subfolder). The intent of the checklist is to help SOP editor bring their document up-to-date meeting SOP GEN006 requirements. The filled out checklist should be reviewed by the SOP editor and second reviewer for completion prior to submitting it to the CRL QA Coordinator. Refer to GEN006 for instructions on which SOP checklist to use.

9.4.5. SOP Routing, Approval, Tracking

9.4.5.1. Routing & Approval

SOPs are updated and routed for review and approval via Qualtrax. Once the updated SOP is published in Qualtrax, all SOP users must be informed of SOP changes in the new version. Once the SOP is published, the file is released into circulation. A New Document Version Record (NDVR) is release after publication to inform all users of the changes to the SOP. For additional procedural details, refer to SOP GEN006.

9.4.5.2. Revisions & Tracking

SOPs are revised biennially, normally early in the year, but can also be updated earlier as needed. The CRL QA Coordinator tracks SOP revision records based on the previous year's annual SOP revision spreadsheet record. The original SOP are electronic and located in Qualtrax. Refer to SOP GEN006 for procedural details and additional information concerning SOP review, revisions and tracking.

9.4.6. Uncertainty Determinations

Policy 019: CRL analytical SOPs shall apply the following uncertainty determinations practice.

[1]*The laboratory is only responsible for estimating the portion of measurement uncertainty that is under its control. Test reports shall include a statement of the estimated uncertainty of measurement only when required by client instruction. If a project requires measurement uncertainty to be reported, the laboratory shall report the estimated uncertainty based on project-specific procedures or, if not available, any other scientifically valid and documented procedures. The estimated measurement uncertainty can be expressed as a range (±) around the reported analytical results at a specified confidence level. The laboratory may report the in-house, statistically-derived BS control limits based on historical LCS recovery data as an estimate of the minimum laboratory contribution to measurement uncertainty at a 95% (2**σ**) or 99% (3**σ**) confidence level.*

For uncertainty determinations procedure, refer to SOP GEN006.

9.5. **Quality Control**

Quality Assurance monitors the processes that support data quality and integrity. Among other relative practices, quality assurance is primarily performed through audits and quality control (QC) procedures. Data audits are conducted which requires that the analyst follow the applicable SOPs for analysis and data verification. Refer to Section 10 Assessment and Responses, for details on Laboratory Audits. This section discusses quality control policy and procedures at CRL.

Policy 029: The CRL shall adhere to the following analytical QC stipulations.

9.5.1. QC Essentials

CRL assures the quality of test analysis and calibration by tracking, monitoring, and evaluating its results with practical quality control limits and documenting data for quality and trends. These procedures include, but are not limited to the following:

- Before an analyst, method or equipment may produce results, documentation of reliability must be presented in accordance with the procedures in Work Instruction, QA-WI002. All SOPs must list the quality control required for analysis with control limits.
- QC sample control charts are generated, reviewed, and evaluated during the SOP revision process.
- Routine use of certified standards for its calibration and quality control standards, secondary reference materials, and certified reference materials.
- Participation in proficiency testing studies. Procedural details are available in QA-WI001.
- Routine replicate analysis: Sample duplicate (Dup) and/or spike duplicate (BSD, MSD) as applicable for the test method and are analyzed per batch (not only upon request).
- Retesting of samples as needed, provided enough sample remains. "As needed" applies to samples re-analysis due to a need for sample dilution, clean-up, etc.
- Reviewing the correlation of data results. For example, the test results for Hexavalent Chromium should not exceed those of Total Chromium in a sample. Another example is the test method results for a soil

[1] US Department of Defense, Quality Systems Manual Version4.1, Washington DC, April 22, 2009.

sample reported on a wet weight basis should not be different than when reported on a dry weight basis according to the percent solids (test) for that sample.
- Perform replicate testing using the same or different methods; mostly due to a client request.

9.5.2. QC Limits

Policy 029-01: Quality control data shall be analyzed and, where they are found to be outside SOP limits, planned action shall be taken and documented to correct the problem and to prevent incorrect results from being reported.

Due to the nature of random outliers in multiple analyte procedures, this policy is extended so as to meet the stated requirement with respects to a consistent QC failure stipulation (policy 029-02), instead of individual QC excursions. This policy exception only applies to multiple analyte procedures in regard to the actions taken to correct the problem. All QC sample failures affecting the data must be flagged to ensure data is reported appropriately. Data Verification SOPs may contain a summarization on qualifiers and can be referred to in the analytical SOP.

Due to this policy, all analytical SOPs have a section addressing quality control and data qualifiers that are assigned when appropriate. The SOP Quality control section addresses the type of QC, QC limits, a procedure for exceeding QC limits correction of problem including documentation, and effects on the data (qualifiers and/or ability to report result). SOPs also include recommended correction of problem(s), herein referred to as on-the-spot or immediate CAs, as well as a general procedure for documenting the correction taken to fix the problem.

Policy 029-01-01: When QC sample results on reported data contain an analyte which failed to meet acceptance limits on a consistent basis (three or more times in a row per final reported analysis), the incident shall be investigated, findings evaluated, and CA taken as appropriate to avoid a reoccurring incident.

When investigating, consideration should be made to removing these analytes from the SOP's target list. The consistently failed QC only apply to reported data that are affected by such exceedance. If the consistently failed QC measure doesn't affect the reported data (e.g. ubiquitous metals detectable at low levels in a blank), then it does not present an issue. QC excursions are instrument specific and not analyst specific issues. For instructions on how to identify and address such a situation, refer to group specific data verification SOPs. Incident investigation, finding evaluation, and CA taken shall be documented and the location of such documents shall be cited in the data verification SOPs.

9.5.3. Sample Duplicate Difference

Policy 029-02: If the difference between duplicates is less than the detection limit, the duplicate difference shall be considered acceptable, even if the Relative Percent Difference (RPD) is not within the calculated limits.

9.5.4. Calibration

Policy 029-03: CRL instrument calibration shall follow the stipulations provided below.

9.5.4.1. Storage of standards and reference materials

All calibration standards and reference materials shall be stored as stated in the SOP to protect the materials from degradation and contamination.

9.5.4.2. SI units

Information is provided in section 9.6.4.1.

9.5.4.3. Instrument calibrations

- Calibration type – Instrument test method calibrations are based on the specific method requirements.
- Calibration use – The entire laboratory will calibrate all analytical instruments and meet the requirement criteria in accordance with the method SOP before analyzing samples.
- The calibration will be analyzed with the same instrument conditions as the samples. Calibration standards will not be taken through all the sample preparations steps unless stated in the method.
- Calibration calculation – Calibrations will be calculated using linear regression, preferably weighted. Exceptions to this stipulation such as using the average response factors calculated using all standards or quadratic equations are permitted so long as the acceptance criteria verifies the fit of the curve. Note: Quadratic equations will not be used after an inflection point or when they approach a horizontal asymptote. Linear regression and its acceptance criteria shall be documented in the SOP.
- Calibration frequency – Calibrations shall be done at the frequency specified in the SOP and reference method. Calibrations may be used for extended periods of time when permitted in the analysis SOP and when verified by continuing check standards. Note: Instrument calibration intervals shall be equally or more stringent than the recommendations made by the instrument manufacturer.
- Calibration verification – Calibrations will be verified at least once by a standard from a separate source, if possible, or a separate lot number, if another source is not available. If a supplier has a "second source" program, that will be considered as intended, as a second source of a standard. Instrument calibrations are checked according to the analytical SOP directions. The calibration checks shall include or exceed the following scenarios and frequencies: After any instrument shut down or substantial maintenance (including instrument service).
- Calibration standards – All manufacturers providing standard reference materials, especially when used to calibrate instruments, must be ISO 17025 accredited. CRL does not calibrate reference standards.

9.5.4.4. The lowest standard

The lowest standard will normally be at the reporting limit. For ICP-AES analyses, where only two standards are used to adjust the calibration equation, a check standard at the reporting limit must meet audit limits or else data may be flagged, or the affected samples may need to be re-analyzed. Calibration equations will be developed for each instrument before any analyses are done.

9.5.4.5. Highest and lowest calibration standards

The highest and/or lowest standard(s) may be dropped from a calibration provided the following provisions are met.

- Appropriate adjustments are made (e.g. increasing the RL and/or apply dilutions as needed).
- No middle calibration standards are removed.
- A minimum of five (5) calibration points for a linear model or six (6) points for a non-linear model remain after the removal of the high/low standard(s).

In multiple-analyte analyses, the standards may be considered as applied to each analyte separately. If the lowest standard is dropped, the reporting limit must be raised to the next higher standard. If the upper standard is dropped, samples must be diluted to below the highest acceptable standard.

9.5.4.6. Middle calibration standard not dropped

No middle standards may be dropped, only replaced with another analysis of the same level standard with a documented explanation in the data package. If a continuing calibration fails after on-the-spot CAs, the instrument must be calibrated again with a full set of standards. Adding a replacement standard is not permitted in this circumstance.

9.5.4.7. ICV and CCV standards

- ICV

Policy 029-03-01: A calibration (standard) shall be verified with a second source standard after each calibration curve and according to the SOP. The second source is recommended to be analyzed immediately after each calibration curve.

An ICV is normally a second source standard used to demonstrate that the instrument calibration source is capable of acceptable performance. The ICV should meet the limits stated in the SOP. Multi-analyte SOPs must ensure an acceptable failure criterion for ICV analytes is limited to 10% of the reported target analytes. When QC analytes exceed acceptable limits, refer to the pertinent analytical SOP for immediate action procedures including the documentation of such CAs. When the ICV fails despite immediate CA attempts, the affected data may be reported semi-quantitatively (qualified). These out of control analytes should not repeat QC limit exceedance consecutively (3 times in a row) per instrument. For more details concerning consistently failing QC, refer to section 9.5.2.

- CCV

Calibrations that are stable for more than one day will be checked with a CCV each time that calibration is used. A continuing calibration verification will be analyzed at the frequency stated in the analytical SOP.

A continuing calibration verification alone will not be used to generate quantitative analytical sample results; a set of valid calibration standards will be used to generate all field and QC sample data.

If a continuing calibration verification is greater than the upper control limit (high bias), sample values associated with that CCV that are less than the detection limit or reporting limit depending on the client request may be reported without extra qualification other than “U”, under the limit for reporting a value.

If a continuing calibration verification is less than the lower control limit (low bias), values more than the reporting limit may be reported with an “L”, low bias, flag without reanalysis.

A continuing calibration verification sample will be analyzed and pass limits at the end of every analytical sequence. The effect of a final CCV will be evaluated to determine if wider limits are needed to prevent loss of useful data.

9.5.4.8. Tune Verification Practices

The amount of tuning compound injected will be the amount stated in the SOP as incorporated from the reference method. Averaging over the entire scan is allowed if stated in the reference method. The SOP will state whether tuning should be done every 12 or 24 hours as required by the reference method. If not averaged, the scan selected will be located at not less than 75% of the maximum peak height. Any background correction applied should be within 20 scans of the tuning compound peak.

9.5.5. Method Detection Limit

The MDL is the minimum concentration of analyte that can be identified, measured and reported with 99% confidence that the analyte concentration is greater than zero.

Policy 029-04: A method detection limit with precision and accuracy studies must be performed and approved before the analytical SOP may be used, and repeated for any major SOP revision.

These studies evaluate whether the reporting limits and calibration standard concentrations are appropriate, among other things. This policy falls in line with policy 010, IDOC. MDL studies apply to an analytical test but not a particular analyst. For an analyte or analyte class, studies are undertaken for each matrix, sample preparation, and instrument combination. For MDL procedural instructions, refer to QA-WI005.

MDL studies are completed according to the latest version of 40 CFR Part 136, Appendix B, unless specified by the SOP's reference method or a specific alternate procedure is documented in the CRL SOP (non-regulatory methods only). Currently MS005 and all Organic Method (OM) SOPs addresses specific MDL procedures. Some methods do not require an MDL because the determinative step is not amenable to the procedure. These exceptions are designated within the individual SOPs and summarized in the table following.

CRL methods not amenable to a MDL:

AIG002 -pH in Water	AIG016 - Density
AIG003 - pH in Waste	AIG019 - TVS
AIG004 - Acidity in Water	AIG024 - Specific Gravity
AIG006 – BOD	AIG038 - Particle Size
AIG008 - pH in Soil and Waste	AIG047 -PM10 & PM2.5
AIG009 - TOC in Soil	AIG048 -Flashpoint
AIG010 - Paint Filter Liquid Test	Metals026 - Hardness (analyzed by Metals003/003A)
AIG015 - Water Content	Gen019 - TCLP (analyzed by Metals003/003A)

Note: This table is subject to change upon the addition of new methods.

Policy 029-04-02: For methods that report results below the reporting limit or are required by regulation to have a routine MDL study, MDL studies shall be performed according to the frequency set by 40 CFR part 136 Part B. If not reporting results below the reporting limit and a routine MDL study is not required by method regulation, then an annual reporting limit verification and evaluation applies.

Note: Regulatory methods may require more frequent MDL studies.

9.5.6. Reporting Limit (RL)

Policy 029-05: All analytical SOPs shall contain a reporting limit which is either defined by the reference method or based on the CRL guidance for the analytical test, per matrix and preparation technique.

CRL generated RLs may be established either as a function of the MDL (e.g., RL =3-10x MDL) or based on the analyst's professional judgment and experience with the procedure and equipment. The RL is normally the lowest level that CRL reports for an analysis, except for special requests. This is because the RL has realizable accuracy audit limits; in contrast, the method detection limit (MDL) does not. For procedural instructions concerning CRL guidance for RL determinations, refer to QA-WI005.

Policy 029-05-01: CRL only reports data to the RL unless specified by a client request.

Regulations may require successful completion of MDL studies (e.g., NPDES). No data generated using such regulatory methods will be released below the reporting limit for methods without documentation of MDLs that meet the criteria described in 40 CFR Part 136 Appendix B.

9.5.6.1. Verification

CRL's SOPs require RL verification as defined by the method or when used as an alternative to MDL study. Some SOPs do not require RL verification because the determinative step is not amenable to the procedure and are listed in table provided in the MDL section of the QMP (Subsection 9.6.4). RL verification is performed by a standard used to demonstrate analyte recovery at the RL listed in the SOP.

RL verification procedures, including frequency of RL verification standard analysis, acceptance and evaluation criteria shall be documented in the analytical SOPs. Documentation for RL verification procedures new to the test methods shall be phased in during annual SOP revision time frames. In the interim, the following guidance statement will be applied to SOPs amenable to RL verification that include no documented procedure or criteria.

For RL verification procedures (section 3), documentation (section 4) evaluation with acceptance criteria (section 5), refer to QA-WI005.

9.5.7. Reprocessing Data

Policy 020: When chromatography instrument software fails to generate a valid peak area, manual integration shall follow SOP GEN029, Chromatographic Peak Integration Procedures.

This policy applies to all Gas Chromatography (GC), GC/Mass Spectrometry, High Performance Liquid Chromatography and Ion Chromatography data that require manual integration according to the analyst's professional judgment. If any other instrument software, now or in the future, requires quantization through peak area integration, analysts are required to follow SOP GEN029.

9.5.8. Expired Material

Policy 031: CRL does not allow the use of expired materials.

All expired reagents must be either discarded appropriately (use of labeled carboys) or taken out of circulation. For procedural instructions concerning the removal or discarding of expired reagents and storage of acceptable expired materials, refer to SOP GEN026.

9.6. Reporting Data Results

9.6.1. For opinions and interpretations of data, refer to section 10.9.

9.6.2. MDL-to-RL Results

When qualitatively confirmed results are found in a sample between the MDL and RL, one of two actions may occur depending on the needs (DQOs) of the client. If the client's DQOs specify CRL is to report as low as possible, the sample result will be reported with the value found and a "J" flag to indicate values falling between the MDL and RL are considered estimated. If the client's DQOs specify an objective at or above the

RL for the parameter, the analyst will report the RL and a "U" flag indicating the sample result is not detected.

9.6.3. Significant Figures

Significant figures for each method will be determined using professional judgment and analytical experience. The number of significant digits will be the same or less than the least precise measurement value in the analysis.

9.6.4. Measurement Traceability

Policy 032: Analytical measurement shall be traceable by following the provided stipulations.

Following are measurement traceability policy stipulations.

9.6.4.1. SI units

All calibrations (and measurements) shall be traceable to the International System of Units (SI). Quick on-line reference: http://physics.nist.gov/cuu/Units/units.html. Standards used at the laboratory shall be from vendors that are both certified and traceable to SI. For exceptions to this policy where calibration is not made in SI units, such as the measurement of pH test methods, the calibration shall provide traceability in confident measurements through its standards by fulfilling the following: Using an approved CRL test method and certified reference materials.

9.6.4.2. Document completely and in real time

CRL data verification SOPs and checklists guide second reviewers and ensure that all information required for measurement traceability is present. Observations, data and calculations shall be recorded at the time they are made and be identifiable to the specific task.

9.6.4.3. Permanent pen use

All observations and data will be recorded immediately in permanent pen with enough information to identify the sample, work order and analysis. Pencils and posted notes are not allowed.

9.6.4.4. Manual corrections

Policy 032-01: Changes to any data record, other than manual integrations, shall be initialed and dated individually.

If several corrections are necessary in a data record, the data must be reprocessed to correct errors. Only one line will be used to strikeout an error. Errors other than transcription should have a reason for each change.

9.6.4.5. Gaps between analysis

Policy 032-02: Gaps in sequences or other indication of discarded analyses shall be documented with an explanation of why the analysis was aborted or entirely discarded.

Analyses leading to reported dilutions should be retained. This policy is in line with policy 013-02.

9.6.4.6. Rejected sample results

Sample results not used to support or report data are included with other supporting data (electronic) and backed-up to the "I" drive where the reported (used) data results are also located.

9.6.5. Manual Integrations

All manual integrations on demonstrations of capability, method validation, calibration standards, performance tests, surrogates, QC standards and spikes will have full manual integration documentation. See SOP GEN029 for detailed instructions.

9.6.6. Adjustments to Data Values

9.6.6.1. Blanks

According to EPA policy, blanks values are not subtracted from analytical values. An exception is 40 CFR Part 50 Appendix G, air filter analysis method permits subtracting filter blanks. If a blank is contaminated the analytical data will be qualified. See data verification SOPs for details.

9.6.6.2. Matrix spike

Sample values are never adjusted for matrix spike recoveries. Clients may be warned in the narrative that recoveries were not within limits and the data should be used with caution.

9.6.6.3. Dry weight basis

All solid sample values are corrected to a dry weight basis unless specifically requested by the client.

9.6.6.4. No correction factors

CRL does not use correction factors for any of its current methods. Should a future method's calibration require a correction factor, the relevant SOP shall address a procedure for applying correction factors and ensuring accurate updates to software file copies.

9.6.7. Recording Dilutions

Standard Practice 003: Dilutions will be recorded on bench sheets or supporting data and in LIMS. On bench sheets, the actual volumes should be documented as a fraction equation (example 5/100) with units, meaning 5 mL are put into a total volume of 100 mL. If the units on each are different, include them, for example, 200 mL in 1 L. Ideally, the dilution factor is added to the dilution column in LIMS, if not already entered when the data is imported in DataTool. This dilution factor or ratio would be five (5) in the last example. Once the actual volumes are recorded, preferably on the bench sheet, the analyst may use other designations such as 5x in other records.

Matrix spikes will add as little volume as practical in order not to modify the matrix. If the volume added is 1% or less, no volume correction is required.

9.6.8. Qualifiers

CRL policy is for analysts to generate data of the highest possible quality to satisfy our client's data requirements. When data quality problems are found, if repeat preparation and analysis are possible to improve quality, CRL analysts will repeat the preparation and analysis. If repeat analysis conflicts with meeting a client's time requirement (turnaround time), the analyst will discuss the situation with the CRL Deputy Director or CRL Director. Commonly used qualifiers in CRL which are also consistently used in the other 9 EPA regional laboratories by agreement are listed below. Other actively used qualifiers exist, but are not listed here since they are customized for CRL purposes and can be found in the LIMS and the end of each client report.

Qualifier	Definition
*	This quality control meets the requirements of the CRL SOP for this analyte.
J	The identification of the analyte is acceptable; the reported value is an estimate.
K	The identification of the analyte is acceptable; the reported value may be biased high. The actual value is expected to be less than the reported value.
L	The identification of the analyte is acceptable; the reported value may be biased low. The actual value is expected to be greater than the reported value.
MI	Matrix Interferences
N	There is presumptive evidence that the analyte is present; the analyte is reported as a tentative identification.
NJ	There is presumptive evidence that the analyte is present; the analyte is reported as a tentative identification. The reported value is an estimate.
Q	QC limit exceeded
R	Rejected
U	The analytes was not detected at or above the reported limit.
UJ	The analyte was not detected at or above the reported limit. The reported limit is an estimate.

All values between the detection limit (MDL) and reporting limit (RL) will be flagged as estimated (J). Quality control information will be included at the program or client request. All values will be reported using a reporting limit unless lower values are requested by a client. Preliminary electronic results will be clearly marked as preliminary, subject to change, and that the final results are to follow.

Clients are requesting electronic data deliverables (EDDs). These may be generated from LIMS at the same time as the final report. In any case where there is disagreement between the electronic version and the paper version, the paper version is considered correct. EDDs should be stored electronically with the supporting data. EDDs should be transmitted to the CRL Data Coordinator or her alternate for transmission to the client just like final paper reports.

9.7. Data Verification

Data verification is a process of evaluating completeness, correctness and conformance/compliance of a specific data set against the SOP requirements. For sample analysis, this is documented by the analyst performing the sample analysis and a second reviewer trained on the analytical instrument used to generate the data. The analyst and a second reviewer (by attesting to the verification of the data) document technical quality of the analysis. Acceptability of data generated will be checked against quality control acceptance limits. The analyst performs the initial data verification by ensuring the analytical SOP was properly followed during laboratory analysis and later when compiling the data package and completing a data verification checklist (found in the applicable data verification SOP). The second reviewer also verifies the data against the SOP during their review and completion of the data verification checklist. In addition, the analyst and second reviewer review the data against the project QAPP (or Sample Plan) DQOs. Any data quality determinations are documented in the analysis case narrative which is part of the LIMS report that is stored in the original data package and submitted to the client. In short, data verification is documented in a data verification checklist by the analyst and second reviewer trained on the analytical instrument used to generate the data.

Detailed group specific data verification information and procedure, including checklists, is available in the analytical group's Data Verification SOPs. Data verification coding procedures and qualifiers are also found in the data verification SOPs. The qualifiers provided are consistent with consensus conventions used by all ten Regional Laboratories.

CRL does not perform data validation or assessment.

9.7.1. Responsibilities

Analyst and second reviewer must then …

- Be qualified
- Review and verify all of their assigned and/or generated data, including supporting data, to ensure data, QA, and QC completeness and correctness.
- Ensure the CRL QMP policies/procedures and appropriate SOPs (preparation, analytical, data verification, etc.) were followed.
- Review any specially-requested information or limits designated in the DQOs and make sure it was addressed in the case narrative.
- Ensure any documented deviations (pen&inks, client contact records, etc.) are applied and/or only current version of any approved spreadsheet (or equivalent) is used, when applicable.
- Sign (or initial) and date the data verification checklist upon satisfaction. Analysts should submit this checklist along with the completed package to a second reviewer trained on the analytical instrumentation used to generate the data package. After any verification comments have been addressed to satisfaction, the second reviewer should sign the checklist.
- Manually update the status of the data in LIMS to reflect the data's current review step. Options include: 'In-Review' (data's second review), 'Review-Edit' (addressing in-review comments), 'In-Review2' (ensuring in-review comments were addressed), and 'Reviewed' (second review is complete). The In-Review and In-Review2 status should be updated by the primary analyst while the second reviewer does the Review-Edit and Reviewed status.

9.7.2. Completeness

The analyst and second reviewer ensures the highlighted responsibilities in section 9.6.3 are met. Any data verification comment(s) is returned to the analyst. Once all on-the-spot CAs, if any, are completed by the analyst, the second reviewer will assure that all documentation is appropriate to the work done and then set the LIMS analytical status to ‘reviewed’ and the analyst will generate a final report for the analysis to complete the data package.

The CRL Deputy Director reviews all final case narratives for clarity and consistency before the pertinent data is transmitted. After the second review by a peer is completed, the analyst submits the case narrative to the CRL Deputy Director via Case Narrative workflow. Once the workflow is approved, the analyst may submit the pertinent data for transmittal. If significant corrections are required, a corrected narrative should be returned to the Deputy for additional review. Otherwise, mild corrections are stated in the workflow comment field. The CRL Data Coordinator is carbon copied on all approved case narrative workflows email notifications for data package administrative review purposes. All case narratives approved by the CRL Deputy Director are stored in Qualtrax as original files until their record retention schedule due dates are up. For additional record retention information, refer to section 6.4.2.

When the analyst and second reviewer’s signs or initial, and date the data verification checklist, he/she is agreeing to the data verification of the analysis and complying with the responsibilities listed in section 9.6.3. This signature or initials also verifies that any on-the-spot CAs were performed addressing review comments before the data was transmittal to the client by the CRL Data Coordinator. It is recommended the second reviewer’s signature or initials and date be done after the final report is generated so as to confirm the ANAB logo was used appropriately. Data packages are released by generating the final report, and by signing the data verification checklist and final data report page(s) as appropriate.

9.7.3. Calculations and data transfer

9.7.3.1. Spreadsheet use – Any calculations done using approved spreadsheets must be made in the latest, controlled version, located in Qualtrax.

9.7.3.2. Raw data transfer – Manual or direct (automatic) data transferred to LIMS is done according to instructions in the analytical SOP.

9.7.3.3. Verifying data results – Analyst and second reviewer are responsible for checking data calculations including data transfers. This responsibility involves the following:

- Comparing the SOP calculations (sample and QC) against the instrument result, spreadsheet and/or LIMS final result for correct value determinations
- Comparing the raw data (instrument or bench sheet) to appropriate initial fields in spreadsheets and/or LIMS for accuracy
- Comparing the original data against the transferred data into a spreadsheet and/or LIMS (including concentration values, retention times, peak areas, instrument name, data & time of analysis, analyst initials, etc.) for accuracy
- Confirming correct dilution factors and affected fields (final results, MDL, RL) in LIMS
- Confirming correct unit conversions
- PT Reviewing Details (applies to hard copy or electronic/on-line)
    - 100% of all PT sample analytes must be reviewed by the analyst and second reviewer
    - Check for accuracy by reviewing each analyte result from the raw data against LIMS and the PT reporting form. Refer to QA-WI003.
    - PT reporting forms should be completed by entering a response for every field, except for those that do not apply such as NELAC Codes inquiries as CRL is not NELAC accredited.
- LIMS Reviewing Details
    - Uploaded Data – For multiple analyte methods consisting of more than six (6) analytes, confirm all positively identified sample data by checking the raw data against LIMS entries. QC data is checked from raw data to LIMS entries periodically according to data verification SOP. For single analyte methods or methods consisting of less than six (6) analytes, confirm all raw data including samples and QC against LIMS entries.
    - Manually Entered Data – Confirm 100% of raw data (sample and QC) against LIMS entries

9.7.4. Resolving issues

Resolving issues generated from data verification comments is the responsibility of the analyst and second reviewer. The analyst is responsible for resolving any questions that the second reviewer might have and the second reviewer is responsible for presenting coherent technical comments to the analyst. If issues are found that cause the usefulness of the data to be in question or issues are difficult to resolve, the second reviewer and analyst together should consult with the CRL Deputy Director and the CRL QA Coordinator when appropriate. When issues concern QA/QC, the CRL QA Coordinator should be present. In the few cases where it may be necessary to attach review comments, a reference to the attachment must be made on the data verification checklist.

9.7.5. References

The CRL data verification process is described in SOPs GEN005 (metals), GEN009 (VOAs), and GEN010 (ABNs), GEN015 (A&I), GEN024 (Air), and GEN016 (GC). Also, SOP GEN029, Chromatographic Peak Integration is used.

9.7.6. Completions

The data package goes to the client through the CRL Data Coordinator. The analyst has the responsibility to give the completed, reviewed and signed (or initialed) data package to the CRL Data Coordinator for distribution. The CRL Data Coordinator will log the data package for record keeping, complete a detailed, administrative checklist of the contents and distribute the data package to the appropriate recipients.

9.8. Releasing Data

9.8.1. Reviewing data

Data packages are released by each analyst after review by a second analyst and any changes, if needed, have been completed and verified. The second analyst and analyst's signatures or initials on the data verification checklist releases the data giving technical approval.

Policy 021: An analyst and second reviewer signatures or initials and date shall be documented on the data verification checklist for the data to be released.

9.8.2. Third administrative review

A third, administrative check using a checklist is performed by the CRL Data Coordinator or her alternate. This signature releases the data for transmission to the client.

9.8.3. For data package and final report requirements for data transmittal, refer to Section 6.11 and GEN032.

9.9. Process Control

Beside the internal peer review for each data package, the CRL QA Coordinator will select already transmitted data packages to perform technical reviews during annual SOP activity audits. These data packages are reviewed against the appropriate analytical and data verification SOPs using a CRL QA Coordinator's SOP audit checklist. The reviews should verify that SOPs reflect current practice. Any problems or non-conformities are reported to CRL management for resolution with the analyst. For procedural information, refer to SOP GEN030.

9.10. Control of Nonconforming Work

Policy 022-01: When a CRL policy or procedure is not followed, control of nonconforming work or CA must be implemented.

9.10.1. Background

Essentially nonconforming work and CA are one in the same with the exception of the initial procedural step. CA procedures are first processed by the QA Coordinator and then reviewed by the Deputy Director whereas the nonconforming work report (NCR) is processed in reverse. Either way, both parties are notified by Qualtrax as soon as a workflow instance is opened. To address nonconforming work, CA is applied. The difference between these two (2) procedures is defined by the nature of the incident which can many times overlap. CAs are respond to audit non-compliances or technical findings most of which may require a root

cause analysis. Nonconforming work is initiated when internal policies/procedures do not go according to plan for various reasons and normally do not need a root cause analysis since the root cause is either out of CRL's control or very simple to determine. This section covers nonconforming work. For CA information, refer to section 10.7.

Nonconforming work essentially occurs when there are unintentional deviations affecting routine policies and procedures at CRL. This can occur at various places within our management and technical (analytical work) system. For unintentional and planned deviations definitions, refer to section 9.10 and 6.3.4 respectively.

Some examples of such deviations are as follow: Samples arriving incorrectly preserved or damaged, chain of custody inconsistencies with tag IDs, sample volume running out due to unforeseen circumstances, client complaints, instrument calibration issues, PT procedure not followed according to internal policy, supporting equipment shown to be defective or outside specified recertification limits, a LCS with zero recovery causing analyte(s) to be rejected in the final report, instrument suddenly temporarily out of service due to inability to function properly giving suspect data results, etc.

With the exception of analytical SOP control limit exceedance as noted directly below, nonconforming work occurrences shall automatically follow the system described in this section in order to control the situation appropriately and in accordance with section 4.9 of ISO 17025.

Note1: Analytical SOPs contain approved immediate actions for quality control limit(s) exceedance. Approved directions on qualifying data for such immediate actions are found in the group's data Verification SOPs: GEN005 (Metals), GEN010 (Organics), GEN015 (A&I), GEN016 (GC), and GEN024 (Air VOA).

Note2: MoBio and OM groups are exempt from this procedure so long as their SOPs are not covered under the laboratory accreditation scope and the nature of the project is research (as noted on the case narrative of the reports).

9.10.2. Procedure

Once nonconforming work is identified, the following procedure shall be immediately administered. For Qualtrax NCR workflow instructions, refer to QA-WI018.

9.10.2.1. Initiate a Qualtrax NCR workflow instance and as necessary stop routine work procedures.
9.10.2.2. Submit a NCR via Qualtrax workflows and contact the appropriate (i.e. client) and affected (i.e. CRL staff) parties.
9.10.2.3. The CRL Deputy Director shall evaluate the incident via workflow procedure. If the nonconformance can recur, or doubt about compliance of the CRL operations with its own policies and procedures exists, a formal CA route shall be selected for the workflow. Note: For emergency response type of projects, formal CA routing may not be a conducive or practical option when the reason for the reoccurring nonconformance in not within the laboratory's control (on client's end). In such a case, constant communication to resolve the issue both immediately and long-term still applies but a report of all the nonconformances should be provided to the client at the end of the project for their consideration to perform a root cause analysis and resolution.
9.10.2.4. The decision made by the CRL Deputy Director on how to correct, continue and/or accept the nonconforming work shall be implemented immediately.
9.10.2.5. Responsibility for recalling or resuming work shall be defined by the CRL Deputy Director and documented in the workflow procedure.

Note: When issues concerning sample login arise, the Sample Custodian (or back-ups) may continue sample login to LIMS after initiating the NCR workflow and notifying all appropriate parties (section 9.10.2.2). The incident response and/or clarification (by the CRL Deputy Director and/or Client) will be applied before impacted samples are made available for analysis.

10. **Assessment and Response**

10.1. Continuous Assessments

To ensure that CRL's policies and procedures are current and consistent with the national and regional policies, the CRL staff work with national and regional offices to obtain both internal and external reviews of CRL operations. This section describes the various assessment tools used by CRL to improve management and QA system, and the response procedures used to correct any problems identified during an assessment.

The following are the primary assessment tools used by CRL

- Management System Review
- Performance Testing (Evaluations)
- External Quality System Audits
- Quality System Audits/Management System Review (QSA/MSR) often met through CRL's "Internal QSA"
- CRL Technical Audits
- [2]Annual review of the CRL QMP for needed updates
- [2]Five-year rewrite and re-approval of the CRL QMP

10.2. Independence

As a part of the United States government, EPA has no functions, other than regulation, that relate to production of goods, commercial marketing, or finance. All Federal employees, particularly managers and TOCORs, are required to disclose any interests they might have in any commercial enterprises. This disclosure includes stocks or other holdings, which might have a bearing on their duties. Financial disclosure statements (OGE Form 450 or OGE Form 450-A) are made annually. All appropriate personnel (Managers, TOCORs, anyone with contracting responsibilities) in CRL complete the financial disclosure form as directed by management following annual guidance from the Agency Ethics Official. These disclosures are reviewed by the Office of Regional Counsel for conflicts of interest. Employees can be requested to divest themselves of holdings that give the appearance of a conflict of interest.

All laboratory audit assessors should not have any real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed.

10.3. Management Reviews

Policy 023: The CRL management shall review and discuss the quality program which include the following practices and stipulations.

10.3.1. Annual management review

Policy 023-01: Yearly (usu. between Nov-Dec), the CRL Director, Deputy Director and QA Coordinator meet formally to review and discuss the quality program.

This annual review is documented and filed in Qualtrax under the Documents/Quality Assurance/QA Coordinator/Audits folder. The annual meeting notes file expires in October on annual basis to the QA Coordinator for editing (to reflect the current year's minutes). This file contains a fixed agenda based on the QMP requirements. Monthly meeting minutes are tracked in a Meeting Minutes workflow instance. Action items and CAs arising from the meeting are documented in the meeting notes, assigned a lead person and

[2] For details concerning QMP review, refer to section 2.2. All other bullets are covered in detail within this section.

deadline appropriate to the nature of action. Note: Annual management review agenda items are many times discussed during regular QA monthly management meetings. Annual management review discussion items include:

- Current policies and procedures; possible new policies
- Reports from managers and supervisors
- Findings of recent internal audits
- CARs/NCRs and their resolution
- PAs
- External assessments, if any
- Proficiency test results
- Changes in the volume and type of work
- *Client feedback including client satisfactory surveys
- *Complaints (staff and clients)
- Recommendations for improvement
- Evaluation of CRL training(s) effectiveness via summary of CARs/NCRs in the QA annual report.
- Any other changing factors that affect quality, such as training, resources or facilities
- Quality policy objectives, as referenced in section 3.5.
- Quality policy statement, as referenced in section 3.2.2.

*Note: Summaries provided by the CRL Sample Coordinator.

10.3.2. Monthly management reviews

Standard Practice 004: Monthly, the CRL Director, CRL Deputy Director and CRL QA Coordinator meet to review and discuss the quality program. This meeting is normally held at the end of the month. The CRL QA Coordinator is the organizer for the re-occurring Outlook calendar meeting. Action items and meeting minute file location are treated in the same way as annual management reviews.

10.4. MSR/QSR

10.4.1. Purpose

A Management System Reviews (MSR)/Quality System Assessment (QSA) is an independent assessment of the organization's quality system. The purpose of the MSR is to evaluate the implementation of the quality system documented in the CRL QMP as well as its effectiveness and sufficiency. QSAs are more focused audits of mature Quality Systems.

10.4.2. Process

Independent, external MSRs/QSAs of the CRL are conducted periodically by Region 5 QA Manager with the RMD QA Manager. A final report summarizing MSR/QSA findings and recommendations is sent by the Deputy Regional Administrator to the CRL Director and to the ARA for Resources Management. The CRL Director will be responsible for ensuring that a CA plan to address the MSR/QSA findings and recommendations is submitted and implemented.

10.4.3. Findings

Findings such as CAs or action items arising from the management system review shall be documented in the review or audit notes with a timescale provided. Refer to Section 10.7 for CAs timescale. Action items are assigned a timescale appropriate to the nature of action.

10.5. Laboratory Audits

10.5.1. Proficiency Testing (PT)

10.5.1.1. Background

Proficiency Testing (PT) programs are used to objectively demonstrate the CRL's ability to perform on routine samples and to investigate the CRL's ability to perform on non-routine samples that is a part of the CRL's core of support. PT providers must be ISO 17025 accredited. Results of these evaluations are used by laboratory management to evaluate technical performance of analytical systems and personnel.

10.5.1.2. Participation Frequency

The CRL participates in one (1) PT study annually for each preparation technique and sample matrix type in accordance with the PT order requirements and determination stated directly below (section 10.5.1.3). Whenever possible, a second PT study is done annually to maintain good practice and monitor the improvement and quality of method procedures. The second PT study will be scheduled with full intentions of completions, but is not required in case of financial or other unforeseen circumstances. See Work Instruction, QA-WI003 for details and forbidden practices.

10.5.1.3. Policy

- Minimum Requirements

Policy 023-02: A minimum of one (1) PT study shall be performed for each current analytical SOP per matrix and preparation procedure within a three (3) year time frame so as to cover all SOPs covered under the laboratory's accreditation scope.

The accreditation Full Re-Assessment year is considered year one (1). A minimum of one (1) PT study will be performed per analytical SOP and matrix annually while alternating SOP preparation methods and/or repeated methods noted as exceptions directly below. Once the laboratory is granted drinking water certification for Metals analysis, the SOPs listed in the pertinent scope of accreditation will participate in appropriate PT studies annually. PTs are obtained from accredited commercial vendors for all available tests. Refer to Section 5.6.2 for a description of an accreditation requirements for a commercial vendor.

- Exceptions to the Requirements

A few analytical SOPs are considered repeated in the laboratory's accreditation scope because the method procedure is almost identical with the exception of some method reference deviations. So long as the technology is the same and the SOP deviations are not considered significantly different from each other, the repeated SOP is considered an exception to the order requirements and does not have to participate in a PT study annually. Rather the SOP should participate in a PT study every two (2) years. Repeated analytical methods are maintained in the laboratory in order to meet client specific requests for method reference analysis. The following analytical SOPs are considered repeats and shall participate in a PT study biennially:

PT SOPs Scheduled Biennially	Description
MS023 (EPA Method 2860) and MS024 (EPA Method 624)	Same technology; different reference method
MS026 (EPA Method 8270) and MS027 (EPA Method 625)	Same technology; different reference method
AIG043B (By Cetac) and AIG043D (By Nippon)	Same technology; different vendor
AIG044B (By Cetac) and AIG044D (By Nippon)	Same technology; different vendor

MoBio & OM group SOPs are exempt from this policy and are not listed under the laboratory's scope of accreditation.

Some SOPs do not participate in PT studies due to the fact that there is no known vendor who provides PT for that specific test method or analyte.

- For the PT order determinations procedure, refer to QA-WI003 section 2.1.

10.5.1.4. Tracking

The PT tracking spread sheet is located in the in Qualtrax under the Quality Assurance folder. The CRL QA Coordinator maintains this spreadsheet. The PT tracking document assures all technologies under CRL's accreditation scope are covered annually giving consideration to different preparations and/or target analytes so that they participate in a study at least once every three years (the complete cycle of CRL's accreditation). In order to document alternating analytical and/or preparation SOPs, the PT tracking spread sheet itemizes analytical and/or preparation SOPs including repeated technology using separate SOP numbers/instrument.

10.5.1.5. Acceptance criteria for multiple analyte methods

- 90% pass rate

Statistics inform us that in multiple analyte analyses (ICP metals, Acid Base Neutrals (ABN), Volatiles, Pesticides, etc.) there will be outliers even when the system is in control. Given such outliers, a pass rate of 90% or more will be considered acceptable for multiple analyte methods.

- Analyte failure

All PT result analytes deemed "not accepted" including SOPs containing multiple analytes which pass at least 90% of the total SOP participating analytes yet still contain some failing analytes, shall be investigated and documented using a CAR workflow. The analyte(s) not accepted shall also be tracked in a spreadsheet maintained by the CRL QA Coordinator in order to determine repeated analyte failure. A repeat PT study analyses may be needed to verify correction of the suspected problem. If the investigation shows that a repeat analysis is not necessary, the reason must be documented in the CAR workflow instance. Routinely, single analyte SOP requires a PT study re-analysis.

10.5.1.6. PT Data Package Review

Results from recent Proficiency Testing samples and data packages should be examined for conformance to the analytical and data verification SOPs. Any questions should be noted for discussion with the analyst. For additional details concerning PT data packages and review, refer to QA-WI003.

10.5.2. Internal QSA

Policy 023-03: An internal system audit in compliance with ISO 17025 Section 4.14 shall be conducted yearly.

According to the ISO 17025 guidance, internal audits include the management system and testing activities. The CRL QA Coordinator performs this internal audit (with assistance whenever available). If the EPA R5 QA staff performs their MSR/QSR that year, it can also meet CRL's internal system audit requirements provided the assessment is performed using the ISO 17025 standards. For the internal system audit procedure, refer to SOP GEN030.

Audit findings result from a process that evaluates the evidence reviewed during an audit against audit criteria such as in house (QMP & SOPs), Accreditation body (ANAB), and/or ISO policies, procedures, standards,

and requirements. Audit findings can show that audit criteria are being met (compliant) or that they are not being met (noncompliant). Technical findings are defined as scientific practices or techniques that met (conforming) good science and/or apply quality to data or lack in characteristic, documentation or procedure rendering the quality of the item or activity unacceptable (nonconforming). Noncompliant and nonconforming findings require investigation and documentation. For more details concerning CAR and NCR, refer to section 10.7 and 9.10 respectively.

Findings can also identify observations concerning future potential issues, best practices or improvement opportunities that are considered for follow up actions but not required. Follow up actions are documented in the Qualtrax Task Request or PA workflow.

10.5.3. External QSA

Policy 023-04: The CRL shall be an accredited laboratory.

According to the Laboratory Competency Policy, the Regional Science and Technology (RS&T) Directors agreed that the Regional Laboratories will apply for accreditation. CRL holds an ISO/IEC 17025:2005 accreditation provided by the Laboratory Accreditation Bureau (ANAB). CRL's accreditation is valid for 3 years from approval. The laboratory accreditation base date is June 10, 2010. Full Reassessment was conducted in 2013 and 2016. For ANAB procedures concerning audit, accreditation requirements, appeal forms, and complaint forms, refer to http://www.anab.org/lab-related-accreditation/lab-related-docs-and-guidance/iso-iec-17025-docs .

Any external Technical Lab Audits from CRL's Regional clients are expected to be conducted in the same general manner as the internal audits.

ANAB annual visits summary:

- Visit Time Frame: 30 days prior to or after (May-July) the accreditation base date.
- Responsible Coordinator: CRL QA Coordinator.
- All visits include on-site witnessing test method procedures and data review/verification.
- Audit findings are documented (LAB Form 33) and CRL must provide formalized responses.
- Year 1 visit: Full reassessment (ISO sections 4&5).
- Year 2 visit: Surveillance visit I-focused on management requirements (ISO sect. 4).
- Year 3 visit: Surveillance visit II-focused on technical requirements (ISO section 5).

10.6. Dispute Resolution

Disputes may arise from many sources. In the CRL, disputes will be discussed internally first. Laboratory management should be involved in early discussions. If the dispute is with someone from outside the laboratory, the Director and CRL Deputy Director may discuss the problem with the person or the person and their supervisor. If these discussions fail to find an acceptable resolution, the Division Directors of the respective divisions may be consulted. Disputes or appeal responses to audit reports are written by the CRL QA Coordinator with consultation from the CRL Director and CRL Deputy Director.

10.7. Corrective Actions (CA)

10.7.1. Background

10.7.1.1. Purpose

At CRL a Corrective Action Report (CAR) is implemented in order to regulate the management system and/or technical operations by means of correcting and/or monitoring a claim of deficiency as well as to

communicate potential problems within and across analytical groups. The purpose of a corrective action is to prevent reoccurring deficiency claim incidents as well as to improve work culture and productivity.

Policy 024: Once a deficiency is discovered, a claim shall be submitted in the Corrective Action Report (CAR) workflow and the provided stipulations followed.

10.7.1.2. Findings associated with deficiency claims

Findings associated with deficiency claims are made during audits or nonconforming work incidents. A finding can stem from various system assessments including, but not limited to data verification, CRL QA Coordinator audits, internal and external audits, client complaints and/or feedback, nonconforming and management reviews, etc. When findings cast doubt on the compliance with policies, procedures, ISO 17025, or validity of results, the lab shall take corrective action and notify clients when the associated investigation affect data results. A claim of deficiency or finding is a discovered practice that reveals:

- Unauthorized and/or undocumented deviations from policies and procedures (finding type: noncompliance)
- Nonconforming work as determined significant by the CRL Deputy Director (finding type: nonconforming)
- Technical findings affecting the data (deficiency claim type: technical)

10.7.2. Investigation and root cause

All deficiency claims are investigated and documented by opening submitting a claim of deficiency in Qualtrax' CA Request workflow. Investigation and root cause analysis (RCA) determine a root cause to which the CA addresses. Some deficiency claims do not require additional investigation (and RCA) other than confirmation of incident, determination of incident impact, and corrective action and due to their transparent nature. The root cause of these type of deficiency claims is easily identified and documented in the CA Request workflow. For additional information and CA Request workflow procedure, refer to the pertinent work instruction, QA-WI004.

10.7.3. Implementing and effectiveness

The action taken to correct the finding and its root cause is documented in the CA Request workflow as the "actions taken." These actions address the root cause so as to avoid a reoccurring incident. Review and sometimes follow-up is required in order to verify and record the effectiveness and implementation of the CA. These actions are documented in the CA Request workflow as reviews (of RCA, root cause, action taken, CA effectiveness) and final approval. During the final approval workflow step, the CRL Deputy Director concurs (or not) with all the documentation and actions provided (including CRL QA Coordinator CA effectiveness recommendation) and either closes the workflow instance or reroutes to additional investigation and RCA.

10.7.4. Monitoring CAs

The CRL QA Coordinator and CRL Deputy Director monitor the status, completion, and effectiveness of all CAs. Should a doubt concerning compliance with policies, procedures, or ISO 17025 still occur towards the end of a CA procedure, an audit or equivalent (returning to CA investigation step) shall be implemented as soon as possible. CAs should be closed within 45 days.

If there is any doubt cast on procedure or policy after the deficiency claim is closed out, the DD can request the CRL QA Coordinator place an audit on the activity.

10.7.5. Documentation – All corrective actions are documented in the CA Request workflow as an instance.

10.7.6. Procedure – When a claim of deficiency is submitted, the first step is to always investigate. For CA and CA Request workflow procedure instructions refer to QA-WI004.

10.8. Clients and Services

10.8.1. Client Services

10.8.1.1. Sample Coordination

CRL Sample Coordinator is available to help schedule, clarify, or answer questions concerning sample analysis. The CRL Sample Coordinator may provide reasonable laboratory access per client requested and need to witness analytical work being performed for their project. The CRL Sample Coordinator and CRL Sample Custodian also work together in order to fulfill additional client needs such as providing test items needed by the client (example: sample containers, pH strips, etc.). Additional client needs are done on a request basis. The ability to fulfill the request is not always guaranteed as desired item availability is a consideration. Refer to Section 3.7.5 for other CRL Sample Coordinator description.

10.8.1.2. Data Coordination

CRL Data Coordinator is available to answer data transmittal questions and requests. *Standard Practice 005*: Requesting data after the addition transmittal has been sent can be done by contacting the CRL Data Coordinator and filling out CRL Form003_Data Transmittal Request.

10.8.2. Client Notification

Policy 025: Clients shall be notified by following the stipulations provided below.

10.8.2.1. Due Dates

If the CRL expects an agreed-upon due date to change, the divisional/program contact will be notified immediately. The contact will be given the reasons for the possible delays and a new date will be agreed upon. Other clients may be asked to change the priorities of their work based on the affected client's needs. If the analysis will be delayed beyond the agreed due date, the CRL Sample Coordinator will discuss the situation with the client and negotiate a new due date. This does not change the due date in LIMS.

10.8.2.2. SOP Pen & Ink Changes

Clients must be notified with an email and/or pen & Ink change (CRL Form001) when changes are made to the SOP which affects their data. For a description of when the data is affected, refer to the details directly below this paragraph. Client acceptance of changes proposed is required before implementing such deviations. The CRL Sample Coordinator, CRL Deputy Director or CRL Director will contact the client depending on the problem, resolution and extent.

SOP deviations "*affect the data*" when there is a change in the laboratory's ability to identify or quantify the analytes in the SOP or when there is a deviation in the regulatory method.

The effective versions of all SOPs are available in pdf format on the R5 Intranet. By submitting an analytical request form, the requestor is implying consent for the use of the appropriate effective SOPs. It is the responsibility of the requester to check the intranet for SOP deviations (known at CRL as 'pen&ink' changes) and version updates. Should the CRL suspect that an SOP deviation affect the data, the CRL Sample Coordinator will contact the requester via email or phone to obtain a consent for the SOP deviation.

10.8.2.3. Analytical Problems

The Group Leader should be notified by the analyst when any problems occur since he/she may provide adequate assistance. The analyst and Group Leader will discuss problems that are not being resolved with the CRL Deputy Director and include the CRL QA Coordinator or CRL Sample Coordinator when needed.

If there is an unplanned deviation with current procedure or instrument problems that are non-routine and/or substantially impacts the data, a NCR must be initiated (see section 9.10) and affected parties, especially the client, notified. When notifying the client, include a discussion about the situation at hand via email and attach the PDF of that message to the NCR workflow. The notification to the client will include what data are/will be impacted, the severity of the changes, and whether the data is/will be usable for the specified purpose. Clients will be notified as soon as the data correction is complete if the data has already been transmitted, ideally not longer than a week from the identification of the problem to CRL management.

10.8.2.4. Exceeding action levels

Clients will be notified when analytical results exceed their action levels, if known, particularly for programs with enforcement abilities.

10.8.2.5. Using samples for method validation

When using old in-house samples for side-by-side comparison studies during method/instrument validation procedures, the analyst should use samples that are ample in volume or weight to assure there is plenty left over. Should the sample volume/weight be in question (for use in side-by-side comparison studies), the client shall be informed to request permission to use the samples. In either case, a memo-to-file should be placed in the pertinent work order documenting its use for these studies.

10.8.2.6. Client Consultation

CRL analysts and the CRL QA Coordinator are available for consultation or questions on work products. Whenever the client data quality assessment requires additional input or analyses, the CRL is prepared to provide assistance. CRL requests feedback from clients after assessment so as to improve services.

10.8.3. Clients Feedback

10.8.3.1. Purpose

CRL uses client feedback used to analyze and improve CRL's entire system, including test method analysis, client services, and its management system.

10.8.3.2. Feedback policy

A client feedback survey is solicited to all clients by the CRL Sample Coordinator after a project event has ended. Client satisfaction surveys include both specific close-ended and open-ended questions as well as a general field in order to capture a variety of positive and negative feedback.

Clients may report inquiries, concerns or complaint via the client satisfaction survey or contact the CRL Sample Coordinator. All client complaints are recorded in Qualtrax with the CC workflow. For workflow instructions, refer to QA-WI012. Complaints are defined as unsatisfactory services to the client. In many cases, an unsatisfactory service may already be tied to an existing NCR or CAR so a new one does not need to be initiated.

Policy 026: Client complaints shall automatically be followed by an initiation of a CA.

The CA can be opened either by the CRL QA or Sample Coordinator.

10.8.3.3. Project completion survey process

A list of project(s) status located in the G share drive (either under CRL Sample Coordinator or Sample Custody) and are updated by the CRL Sample Coordinator in order know when a project event is ending. Once a project event is completed, the CRL Sample Coordinator sends out an electronic client satisfaction survey to the project. The survey is ideally sent with the last data package transmitted or shortly after that. The client responds by completing the survey and sending it to the CRL Sample Coordinator. All client satisfaction surveys shall be maintained by the CRL Sample Coordinator.

10.9. Opinions and Interpretations

10.9.1. Regional staff requests

The goal of the CRL is to deliver analytical data, scientific expertise, and technical skills to meet the needs of our clients. The CRL serves as a resource for information on analytical chemistry and biological analyses. When Regional staff makes a request for an analyst's written opinion, the analysts should consult with the CRL Deputy Director. The request is included in the CRL schedule with his approval. Work products from reviews are the responsibility of the staff producing them. The approval of the CRL Deputy Director to produce the written opinion serves as the approval to release it. Written opinions are submitted to the CRL Data Coordinator for release to the requestor. No reviews or opinions are furnished to entities outside the Agency.

10.9.2. Preliminary results information

Preliminary or verbal results may be furnished to our clients upon request. The CRL Data Coordinator transmits documented preliminary results. Preliminary results are those which have not undergone secondary analyst review. For more details, refer to section 8.2.4 Non-routine work.

11. **Improvements**

Policy 027: Whenever possible, the CRL staff members shall participate in quality system improvement meetings, including but not limited to, preventive actions which follow the stipulations provided below.

11.1. Background

As part of EPA Principles of Scientific Integrity referred to in Section 3.2, CRL continuously strives to improve all aspects of its management system, including its technical activities, through CRL Improvement Team (CIT) meetings, a Data Integrity Plan, PAs, and the implementation, assessment, and response of various assessment tools including, but not limited to, audit results, management reviews, CAs, quality policies. Refer to QMP Section 10 for assessment tools. For meeting frequency and agenda details refer to section 3.11.1 (Internal Communication). For records and details refer to G:\CIT – CRL Improvement Team.

11.2. CRL Improvement Team (CIT)

11.2.1. Origination and purpose

CIT meetings were originally created by the CRL as a response to a High Performance Organization training held at EPA.

The goal of CIT meetings is to improve various components of its management system including its effectiveness and productivity. These components include, but are not limited to, communication across the

laboratory, management, and internal policies and procedures. Management and staff attendance represents their commitment to continually improve the CRL and the effectiveness of its management system.

11.2.2. Meetings

All CRL members are required to attend and highly encouraged to discuss any matters pertaining to the laboratory and its functioning, including the quality system or aspects of such. All members (staff and management) are considered equal during these meetings. These meetings are led by staff members which can include management. Individual meetings are led by an agenda team made up of 3 randomly selected CRL members. CRL members meet to discuss possible laboratory improvements and other related issues.

11.2.3. Retreats

The CIT also occasionally holds intensive retreats where issues are thoroughly examined, and plans of action are developed. The value of these all day retreats is enhanced by the assistance of trained EPA moderators.

11.3. Data Integrity Plan

11.3.1. EPA Defined

The policy of the CRL is to conduct all business with integrity and in an ethical manner. Each staff member and manager shall hold to the highest ethical standard of professional conduct in the performance of all duties. They shall adhere to *U.S. EPA Scientific Integrity Policy* February 2012 https://www.epa.gov/risk/policy-epa-scientific-integrity, included in this QMP.

The EPA definition of fraud is the deliberate falsification of analytical and quality assurance results, where failed method and contractual requirements are made to appear acceptable.

11.3.2. Hiring and Dismissal

Hiring and dismissal policies are codified in the Merit Promotion System written by the Office of Personnel Management (OPM) implementing the Civil Service Reform Act of 1978. EPA implements these regulations with policies. The Region 5 Cincinnati Shared Service Center checks the credentials of candidates and keeps records of official academic transcripts.

11.3.3. Disciplinary Actions

EPA Order 3120.1, the Conduct and Disciplinary Manual, describes policies governing employee conduct and corrective disciplinary actions in the Environmental Protection Agency. A stepped approach to disciplinary actions is outlined based on the severity of the infraction and the number of repetitions. Scientific integrity is covered in the manual.

11.3.4. Open Communication

Laboratory management strives to have an open door policy on all matters, particularly fraud. For those who are not comfortable discussing concerns directly with a manager, there are other routes. The CRL QA Coordinator is available to hear issues. Also, the CRL Improvement Team, CIT, meetings provide an open forum for discussing concerns and problems in the laboratory.

11.3.5. Investigative Procedure

Reports of suspicious practices are initially investigated by the CRL QA Coordinator with verbal and written reports to the Director and CRL Deputy Director. From the initial investigation, management determines the next steps. After completion of a preliminary investigation a determination is made whether to pass the

reports to upper management or the EPA Inspector General (IG). If the incident is not substantiated, no action is taken. If the incident is a misunderstanding, the analyst is counseled by his supervisor in correct procedure. If reports are forwarded to upper management or IG, the handling of the incident leaves the authority of laboratory management.

11.3.6. Protection

Staff reporting severe problems with any government processes is protected by the Federal Whistle Blower Act which prevents retaliation against people who report waste, fraud and abuse. Less globally, CRL supervisors are committed to producing quality data. Staff is expected to report problems on an ongoing basis so that supervisors can assist in solutions where possible. Managers encourage staff to report problems early so that they can be addressed and managed before they grow too difficult proportions. Staff is not criticized for bringing any kind of problem to their supervisors. The CRL QA Coordinator maintains an open office to encourage staff to discuss issues. The CRL QA Coordinator can investigate any quality issue without noting a reason. Frequently, audits result in CAs. These actions are available for all to read in the CA database. Feedback would be through this database for any issues that were not confidential.

11.3.7. Management Investigation Reports

11.3.7.1. Preliminary investigations

Preliminary investigations will be documented as data audits or technical audits depending on the suspected problem. Printed reports are stored with the reviewed data and electronic versions by the CRL QA Coordinator and CRL Deputy Director.

11.3.7.2. No impact on data

Some practices, although not condoned, have little or no impact on the reported data. These practices will be discussed as inappropriate and kept internal to the laboratory. These investigations and resolutions may be conveyed to the person reporting the problem. Any investigations and resolutions that are referred to upper management or the IG will not be conveyed to the person reporting the problem but kept confidential according to Federal guidelines.

11.3.7.3. Administrative disciplinary actions

Administrative disciplinary actions may be taken depending on the severity of the infraction. The first action is private discussions with the person's supervisor. Suspensions, firing and other, more severe, actions require involvement of HR and division management.

11.3.7.4. CAs – Most investigations result in CAs that are entered in our CA database. These CAs will be appropriate to the findings, and monitored by the CRL Deputy Director.

11.3.8. Documented Investigation Process

11.3.8.1. CRL QA Coordinator inquiries

An independent inquiry is conducted by the CRL QA Coordinator whenever there is a report of practices that seem not to follow the laboratory quality procedures. Reports generated as a result of the CRL QA Coordinator investigations are transmitted to the CRL Director and the CRL Deputy Director, supervisor of the analytical staff. If the reports are generated as a result of data or technical audits, the results may be given to the analyst and Group Leader. If the results indicate serious problems, the results are kept confidential pending further investigation or referral to upper management or the IG.

11.3.8.2. Inspector General

If the Inspector General finds sufficient evidence, prosecution is possible. This prosecution is conducted by the Department of Justice and is outside the control of laboratory management.

11.3.8.3. Employee Responsibilities

11.3.8.4. All staff members

All staff in the CRL has responsibility for preserving the integrity and quality of the data we produce. Staff must follow all applicable SOPs for the analyses and reviews that they do. Group Leaders and other staff are available should there be questions or problems. The analyst must ask the necessary questions to get help with difficult analyses. The Group Leaders and experienced laboratory staff are responsible for training new analysts in methods and procedures in their areas of expertise.

11.3.8.5. Analyst communication – All analysts must communicate openly with the CRL Deputy Director about problems and frustrations. The CRL Deputy Director cannot assist with a problem he does not know about.

11.3.9. Instrument responsibilities

Analysts are responsible for maintaining all instruments regularly and recording all maintenance performed. CAs should fix the underlying problems rather than being quick fixes. Taking shortcuts or modifying the practice of an SOP without writing it down and getting approval is not acceptable practice. If an analyst has a better way of doing an analysis it should be tested and written up as a modification to the method SOP. CRL is always looking for better ways. New practices should be discussed with the analytical group for other expert opinions. Risky practices should be reported to the supervisors or CRL QA Coordinator.

11.3.10.Quality Improvement

Quality improvement is a continuing process that involves implementation of recommendations made by the CRL QA Coordinator, scientific staff, support staff and laboratory management. Regular meetings are held in the CRL to foster improvement of the CRL's products and processes. These meetings are supplemented by the assessment and response procedures described in the rest of the Quality Management Plan.

11.4. Preventive Actions

11.4.1. Background – A wide range of CRL activities may identify areas for preventive action consideration. Some of these activities are CRL retreats, annual QA management meetings, monthly QA-management meetings, CIT meetings, group meetings, and internal technical and data audits. CRL uses its Qualtrax PA workflow instances to anticipate and track improvement needs and potential hindrances or nonconformities.

11.4.2. Records – All records are maintained in the Qualtrax PA workflow.

11.4.3. Process – PA are pro-active procedures to improve the quality system, not to be mistaken with reactive corrective action addressing a noncompliance or nonconformance. Improvement opportunity should be brought to the attention of management which can lead to a PA when the CRL Deputy Director or CRL Director assign a staff member to take action. The procedure and documentation is covered in a Qualtrax PA workflow which also applies a control (many times in the form of checklists, spreadsheets, documented instruction, etc.) to ensure the actions are effective. For Qualtrax PA workflow and general procedural instructions, refer to QA-WI019.

References

Coleman, Kathleen and Geoff Cooper. Frequently Asked Questions About Publication Agreements, U.S. Environmental Protection Agency, March 11, 2014. Accessed July 15, 2014. http://intranet.epa.gov/ogc/ethics/docs/Publication-agreement-FAQs.docx

ISO/IEC, (2005). ISO/IEC 17025:2005 International Standard – General requirements for the competence of testing and calibration laboratories. Geneva, Switzerland: ISO/IEC.

Office of Environmental Information. EPA Policies, Procedures, Standards, and Guidance. Available at: http://intranet.epa.gov/oeiintra/imitpolicy/policies.htm. Accessed: 06-12-14.

Office of Environmental Information. EPA Quality Policy. Available at: http://www.epa.gov/irmpoli8/policies/21060.pdf. Accessed: 02-05-14.

Toney, Marcy A. Unaddressed Memo, Ethics Regulations and Writing for Publication, U.S. Environmental Protection Agency. October 19, 2009.

US Department of Defense, Quality Systems Manual Version4.1, Washington DC, April 22, 2009.

U.S. Environmental Protection Agency Peer Review Handbook, 3rd Edition. Washington, DC 20460. Science Policy Council U.S. Environmental Protection Agency. The United States Environmental Protection Agency. Retrieved from http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2012.pdf.

U.S. Environmental Protection Agency, 2006. Peer Review Handbook, 3rd Edition, EPA/100/B-06/002, Science Policy Council, EPA/100/B-06/002. Accessed June 12, 2014.

United States Environmental Protection Agency. EPA's Office of Science Advisory, Scientific Integrity Policy February 2012. Available at: http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf. Accessed: 06-06-14.

United States Environmental Protection Agency. EPA Quality System. Available at: http://www.epa.gov/quality/qs-docs/r2-final.pdf. Accessed: 11-01-13.

United States Environmental Protection Agency. EPA Quality System. Available at: http://www.epa.gov/irmpoli8/policies/21050.pdf. Accessed: 11-01-13.

United States Environmental Protection Agency. EPA Quality System. Available at: http://www.epa.gov/QUALITY/qs-docs/g8-final.pdf. Accessed: 02-20-14.

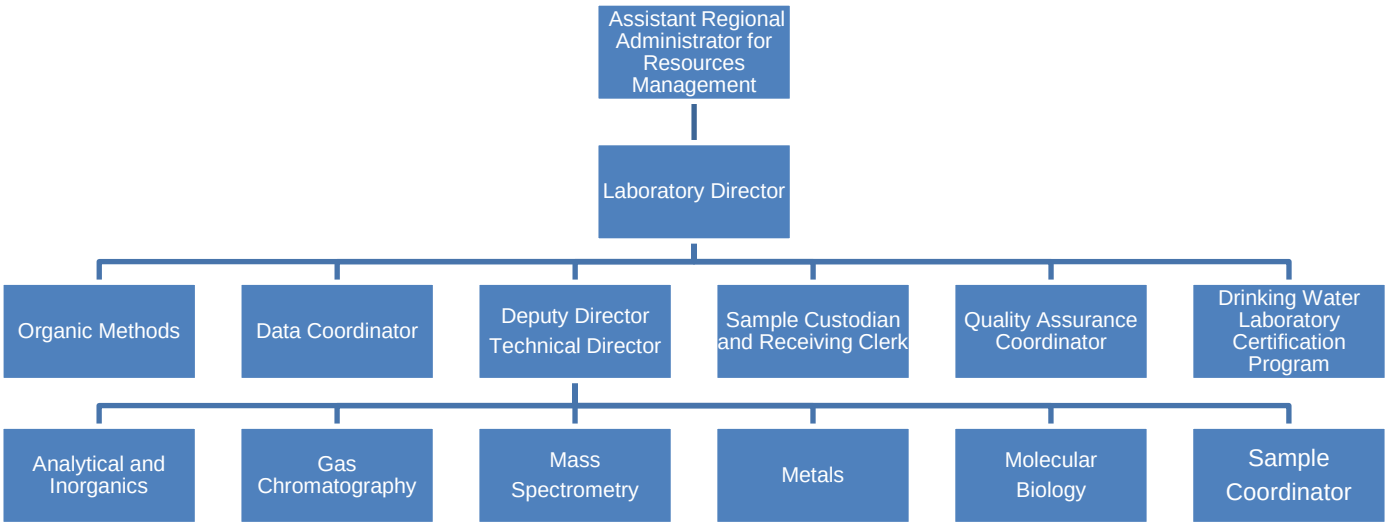
United States Environmental Protection Agency. Records. Available at: http://www.epa.gov/records/. Accessed: 06-12-14.

U.S. Environmental Protection Agency, 2002. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R-02-008, Office of Environmental Information. Accessed June 12, 2014. http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf

U.S. EPA Sampler's Guide Contract Laboratory Program Guidance for Field Samplers OSWER 9200.2-147 October 2014 https://www.epa.gov/clp/contract-laboratory-program-guidance-field-samplers

Appendix A – Organization Chart & Listing of Staff

[Listing of Staff is on next page]



Office of the Director		
Griffin, Sylvia	CRL Data Coordinator	3-9073
Ockrassa Davis, Angela	CRL QA Coordinator	3-7445
Awanya, Francis	CRL Acting Deputy (Technical) Director	6-3682
Snyder, Rob	CRL Sample Custodian and Receiving Clerk	3-9083
Frank Lagunas	Drinking Water Laboratory Certification Program Manager	6-4466
Schupp, George	CRL Director	3-1226
Analytical & Inorganic		
Breslin, Colin	Chemist / Drinking Water Laboratory Certification Officer	6-2912
Fuentes, Nidia	Chemist	3-9079
Knoebel, Anna	Chemist, Acting Group Leader	3-9467
Gas Chromatography		
Larry, Danita	Chemist	3-1161
Santiago, Edgar	Chemist	3-5521
Mass Spectrometry		
Leckrone, Kristen	Chemist / Drinking Water Laboratory Certification Officer	3-9068
Kerr, Michelle	Chemist, Group Leader (GC & MS)	6-8961
Strock, Troy	Chemist	3-8362
Thompson, Robert	Chemist, Sample Coordinator	3-9078
Whipple, Wayne	Chemist	3-9063
Metals		
Mitsakopoulos, Greg	Chemist,	3-0377
Swan, Kathleen	Chemist	3-9071
Wroble, Amanda	Chemist, Group Leader	3-0375
Molecular Biology		
Jastrow, Aaron	Biologist & Group Leader	3-7386
Organic Methods		
Zintek, Lawrence	Chemist, Group Leader	6-2925
Kleinmaier, Danielle	Chemist	3-9771
CRL labs		
All lab rooms	--	3-4350
Contractors		
EnSoftek	Computer Support	3-4357 (3-help)
Massie, Diane	Health and Safety	3-7909
TechLaw Inc.	ESAT, Glassware Services	3-2964
Bonina, Solidea	PTSI Contractor	3-9074
SEE		
Wong, Laurence	SEE	3-8418
Loren, Dinsmore	SEE	3-3594

Appendix B – Listing of Equipment

Please contact Rob Snyder, to access the Financial Data Warehouse, to run a fixed asset property inquiry to find all equipment within a custodial area. Go to http://iasint.rtpnc.epa.gov/neis/property_web.property_inquiry. Choose AA15 Chicago for the ac-countable area and enter the custodial area code 552, 553, and 554 for a listing of all laboratory equipment.

Appendix C – Policies and Standard Practice List

Policy/SP No.	Policy/SP No.	Brief description	[3]Updated Year
Policy 001	001	QMP that is regularly reviewed	2015
	001-01	QMP official 5-year review	2016
	001-02	QMP Annual review	2015
	001-03	QAARWP	2015
Policy 002	002	Policies Effective Date	**2017 R**
	002-01	Policy exceptions or planned deviations (one-time)	**2017 N**
Policy 003	003	Required client documents	2014
	003-01	QAPP & DQOs	2012
	003-02	COCs and ARF (CRL Form 008)	**2017 R**
Policy 004	004	EPA's Principles of Scientific Integrity & QMPs policies and procedures	2014
Policy 005	005	Non-EPA employees	2015
Policy 006	006	Internal communication (meetings)	**2017 R**
Policy 007	007	Timeliness and Due Dates	2015
Policy 008	008	Protecting client's sensitive information	2016
	008-01	CBI documents/certified	2013
	008-02	Media – Reference to RA Public Affairs Office	2014
	008-03	Criminal Investigation Samples (GEN007)	2015
	008-04	Share drive security	**2017 R**
Policy 009	009	Mandatory Training	2013
	009-01	Safety rules and GLP (new 2017)	**2017 N**
Policy 010	010	Demonstration of Capability (DOC)	2015
Policy 011	011	Equipment and Supply Purchase quality & documentation	2014
	011-01	Purchase negatively affecting quality shall be reported	2014
	011-02	Standard reference material traceability	2015
	011-02-01	Standard and reagent LIMS ID requirement	2015
	011-03	Equipment and Supply suitability and storage	2014
	011-04	Equipment and Supply Technical review	2015
	011-05	Vendors to CRL must be ISO 17025 and/or ISO Guide 34	2016
Policy 012	012	Control of QA document (including unique ID)	2016
	012-01	QA document's Unique ID	2014
	012-02-01	QA policy/procedural deviations documented & approved	2016
	012-02-02	Technical data amendments.	2016
	012-03	New document revision notification (and NDVR)	2015
	012-04	Procedural documents used exactly as written	2015
Policy 013	013	Electronic records	**2017 N**
	013-01	Scanned electronic records	**2017 N**

[3] The letter "D," "N," or "R," behind the year means the policy is either deleted, new, or revised.

Policy/SP No.	Policy/SP No.	Brief description	[3]Updated Year
	013-02	Record retention schedules	2017
	013-03	Reconstruction of technical records	2014
	13-04	Gaps in sequences	2015
	13-05	Results entered in LIMS and locked asap	2015
	13-06	Results backed up in the LAN I drive asap	2016
	13-07	Sample tags	**2017 R**
Policy 014	014	Logbooks and Manuals	2015
Policy 015	015	QA documents regular review/revision	2015
	015-01	SOP revision stipulations	2014
Policy 016	016	Hardware & Software	2014
	016-01	Hardware & Software – Retention	**2017 R**
	016-02	Hardware & Software – tested & verified	**2017 R**
	016-03	Hardware & Software – LIMS rights	2016
	016-04	Internet access (limited for instrument PCs)	**2017 N**
Policy 017	017	Sample Handling	2014
	017-01	Samples entered into LIMS w/unique ID and use GEN013	2014
	017-02	Sample temperature exceedance exception	**2017 N**
	017-03	Samples and standards/reagents stored separately	2015
	017-04	Samples (subsampling)	2014
Policy 018	018	Health and Safety	2014
Policy 019	019	Analytical SOP uncertainty determinations	2015
Policy 020	020	Manual chromatography peak integrations GEN029	> 5 yr.
Policy 021	021	Releasing data requirement	> 5 yr.
Policy 022	022	CAR and/or NCR - Policy/procedures not followed	2015
Policy 023	023	Assessments – Management reviews the quality program	2016
	023-01	Assessments – Annual management reviews,	**2017 R**
SP 004	SP004	Assessments – Monthly management reviews	2014
	023-02	Assessments – PT policy	2014
	023-03	Assessments – Internal Audit including	2012
	023-04	Assessments – External Audit	R 2015
Policy 024	024	Assessments – Deficiencies and CA	2014
SP 005	SP005	Assessments – Re-request data using CRL form	2014
Policy 025	025	Client Notification	> 5 yr.
Policy 026	026	Client Feedback including complaints/CAs	2014
Policy 027	027	Improvement – CIT, PA, and data integrity	> 5 yr.
Policy 028	028	Instrumentation and supportive equipment	2014
	028-01	Supporting equipment certification	**2017 R**
	028-02	Balance verification	2014
	028-03	Glassware verification	2014
Policy 029	029	Quality Control	2016
	029-01	QC limits exceedance	2015
	029-01-01	QC sample exceeding limit > 3X in a row	2016
	029-02	RPD	2014
	029-03	Calibration	2016 R
	029-03-01	ICV – second source	2016
	029-04	MDL	2014
	029-04-01	MDL or RL Studies, verification, evaluation	2013

Policy/SP No.	Policy/SP No.	Brief description	[3]Updated Year
	029-05	RL	2014
	029-05-01	CRL only reports to the RL unless requested	2014
	029-05-02	RL Verification	2014
Policy 030	030	Data Packages	**2017 R**
Policy 031	031	Expired Material	2016
Policy 032	032	Measurement Traceability	2014
	032-01	Manual corrections – procedure	> 5 yr.
	032-02	Gaps between analysis	> 5 yr.
SP 001	SP 001	Lab-wide QA document - staff comment and review period	2014
SP 002	SP 002	Housekeeping – lab shall be kept clean and organized	2014
SP 003	SP 003	Dilutions recorded on bench sheets	2014

Appendix D – Revision History

QMP version #6 revision:

Location and Description of [4]Major Modification	Impacted Documents
Entire document – Replaced GEN-WI005 with SOP GEN032 which incorporated both GEN-WI005 and GEN-WI005A.	GEN032
§2.3.5 – Policy 002-01 Newly created stipulation to document one-time policy exemptions and deviations. Addressing 2017 ANAB N/C #4: Approved on 09/26/17 Qualtrax document ID #11612.	Form 013
§2.3.8 – Policy 013 and its stipulations revised to incorporate technical electronic data. This move supports the Managing Government Records Directive issued by OMB and NARA M-12-18 of August 24, 2012.	GEN032 GEN005, 010, 015, 016, 024, 028
§3.1.5.2 – Mildly revised to reflect current practice for DW certification officers.	N/A
§3.7.10 (QMP v5) – The Laboratory Management Assistant position description was deleted as it no longer exists.	N/A
§3.12.3.4 – Policy 008-04 stipulation revised to allow internal share drive folders to be set up by project. All of the share drives/sites used by CRL have security built at the folder level to limit access appropriately.	Possibly data verification SOPs
§4.2.1.1 – 1st paragraph revised to clarify language and added a note for cases where a policy deviation or decision needs to be documented. Addressing 2017 ANAB N/C #4. See Qualtrax ID #11612.	Form 013
§4.2.1.2 – 2nd paragraph; Added language to address analysts assisting with a SOP preparation.	QA-WI002
§4.4.9 & 10.3 – Section 4.4.9 is a new section to evaluate the effectiveness of CRL trainings. Section 10.3 added bullet #11. Both addressing 2017 Internal QSA N/C # 03: See Qualtrax ID #11161.	Qualtrax doc #5188 & 11163
§6.4, 6.5, 6.6, 6.11 – Revised to address CRL's move towards electronic records, including data packages, including revision and addition of policy 013 stipulations. Note: QMP v5 section 6.4.5 was relocated to GEN018 v3. Also, procedural instructions for COCs (6.5) and sample tags (sect. 6.6) have been relocated to GEN013.	Same as §2.3.8 and GEN018 & GEN013

[4] Excluding acronym updates, editorial, reference sections/statements and minor format changes, etc.

§7.1 – Policy 016-01 mildly modified to reflect current practice with regards to retired software.	N/A
§7.2– Also a paragraph (last one) was added to address how CRL maintains control of instrumentation used by ESAT. Addressing 2017 ANAB N/C #01: See Qualtrax ID 11590.	N/A
§7.4 – New section introducing the use of CRL share point site.	N/A
§8.4.1 – Policy 017-02 created stipulation to address current practice for sample temperature exceedance exception. The last paragraph in this subsection was also added to explain the exception to the rule. QMP v5 policy 017-02 is now QMP v6 policy 017-03.	N/A
§8.5.2 – Added last paragraph to reflect current practice regarding safety walk-through audits.	N/A
§9.5.5 – Removed policy stipulation 029-04-01 as it a procedural instruction, not a policy. The removed stipulation is reflected in 40 CFR part 136 appendix B which we reference in the QMP as the procedure to follow. Therefore, stipulation 029-04-01 became 029-04-02.	NA
§9.5.6.1 – Policy stipulation 029-05-02 was removed as it was a duplicate, already covered in QMP v5 stipulation 029-04-02 (language revised for clarity, QMP v6 029-04-01).	NA
Appendix A – Modified to 1) remove the management assistant position from the organization chart. In the staff listing (table) 2) replace Dennis Wesolowski (now retired) with George Schupp as Laboratory Director. 3) replaced George Schupp with Francis Awanya as Acting Deputy Director. 4) replaced Francis Awanya with Anna Knoebel for A&I group leader. 5) removed Linda Telles who retired. 6) removed Thomas Yuen who is no longer working at CRL.	N/A
Appendix C – Update table according to policy changes.	Qualtrax doc ID #4879
Qualtrax Draft redline copy can be found in Qualtrax Draft Document workflow instance #12458.	N/A

QMP version #5 revision:

Location and Description of Significant Modification (Excluding acronym updates, editorial, reference sections/statements and minor format changes, etc.)	Impacted Documents
Entire document (global change) – Replace the word "supportive" with the grammatically correct term "supporting" in its associated use with the phrase "supporting equipment." Impacted documents should be updated according to their revision schedule. Also replaced all L-A-B reference to ANAB as our new AB: Section 2.1.1	GEN026 & Other SOPs
§2.1.1 – Updated our accreditation body (AB) name since L-A-B is now folded into ANAB. The new AB name is effective after the CRL's 2017 Surveillance Visit I (external audit) is completed and the scope of accreditation updated to reflect ANAB. The new logo implementation due date is set by the new AB.	All LIMS reports and SOPs with an AB logo.
§2.3.5 (policy 002) – The current policy now addresses the effective dates of policies requiring an implementation period. Removed the 45-day grace period (QMP v4) since it is no longer needed due to the new policy modification. The policy implementation list (PIL) will also change accordingly as annual summary holding the revision history tables of all QA documents containing policies. Added a grandfather clause that applies to modified/new internal policies.	PIL
§3.7.6.1 & 9.7.1 – Scientific staff members have a responsibility to update LIMS to reflect the current data review step it is on. This change has been effective since 10/24/16; see Qualtrax document ID #8596.	Data Review SOPs
§3.7.6.2 & 3.7.7 – Reflecting current practice – Moved and revised "QA updates" language from section 3.7.7 (last few points) to section 3.7.6.2 (4th bullet, last arrow) as collecting QA doc. review responses for the group is not solely a group leader function rather a group designated member task. Also removed "MDL" and "control" chart language from section 3.7.7 (last few points) as each analyst is responsible for these task through the SOP revision process.	NA

§3.7.8.8 & 6.10.7 – The Sample Custodian must ensure WOs or at a minimum specific analysis sample(s) within a WO are verified as indicated by its 'available' status in LIMS before checking samples out to analysts for analysis. This policy has been effective since 08/17/16; see Qualtrax document ID #8006.	GEN013 & GEN-WI001
§3.11.1.4 – New monthly QA lab-wide meetings to discuss quality assurance issues and upcoming changes affecting the entire laboratory.	NA
§3.12.2.4, 5.4, 5.5.1.1 & 6.4.2.1 – Updated to reflect current practice: Budget (5.4), TAT due dates extension (3.12.2.4), Contract work (5.5.1.1), QAPPs and completed analytical forms (6.4.2.1).	NA
§4.4.6 & 4.4.7 (policy 009-01) – New policy to address following safety rules and GLP. This policy is effective on the date CRL SOP GEN031 v1 is published.	NA
§4.4.7 – Modified the current annual training procedure to include reading a newly created SOP GEN031 and take its associated NDVR test.	New SOP GEN031
§5.2.1 – Some new supporting equipment with qualified certificates may fulfill the life of the newly purchased certification to its expiration date before starting in-house recertification (schedule and frequency). This change has been effective since 09/15/16; see Qualtrax document ID #8261.	GEN026
§5.2.1 – When supporting equipment gives suspect results, is overloaded, mishandled, shown to be defective or outside specified recertified limits, a control of nonconforming work (QMP section 9.10) will be initiated. This practice should already be in place based on the definition of nonconforming work, but documentation was inserted here to meet ISO 17025 section 5.5.7 as a recommendation made from the 2016 internal QSA.	GEN026
§5.2.1 – New language to address shipping supporting equipment.	GEN026 & QA-WI011
§5.2.1 – Removed the requirement to recertify glass syringes based on the CRL's data collected.	GEN026
§6.3.2.1 – Updated language concerning retired documents to reflect current practice.	GEN006
§7.8 (policy 016-04) – New policy concerning internet access and security. This policy addressed a noncompliance in CA #9287 stemming from the 2016 internal QSA.	NA
§8.2.4.2 – Clarified and included the fact that preliminary data is transmitted the same as final results.	NA
§8.4.7 – Delete an inaccurate statement stating that samples are disposed of at the Director's discretion when in practice CRL follows the guideline in GEN013.	NA
§9.5.4.7 (policy 029-03-01) – Revised the current ICV policy for clarification purposes. This change has been effective since 09/15/16; see Qualtrax document ID #8261.	NA
§10.8.2.3 – Revised language to elaborate on the procedure taken concerning analytical problems. This modification also addresses CA #8446.	NA
To review the redline copy of QMP v5, refer to workflow instance #9551.	NA

V = Version, S = Status, R = Revision

V	S	**Location and Description of Significant Modification** (Excluding acronym updates, editorial, reference sections/statements and minor format changes, etc.)
4	R	Entire document – All policy statements have been revised throughout this document, mostly for clarity but sometimes to better address accreditation requirements.
		Entire document – The QMP v3 sections 12-15 have been redistributed throughout appropriate sections 1-11.
		Entire document – The CRL no longer claims to validate data based on agency structural procedures for region 5. Definitions for data reviews, data verification, and data validation have been provided based on the EPA R5 RMD QMP and this entire document has been revised accordingly [CA#6577].
		Entire document – The users of this document should review QMP version 4 in its entirety, especially the revised policies.
		Entire document – For the redline copy of this document version, see Qualtrax document draft workflow instance #7177.
		§2.2.1 – Replace the submittal of the QMP tracked changes with a reference to the revision history appendix 3.

		§2.2 – Updated the latest 5 year CRL QMP review date to reflect 2016 and updated the QMP review procedure to include the QMP revision history appendix (summary of changes).
		§3.1.2 – Separated the Organics group back into GC and MS. Smaller groups worked better.
		§3.9.3 – Added CRL Deputy Director review and approval responsibility for CID technical reports.
		§3.9.4 to 3.9.8 – Reorganized, re-summarized, and when applicable updated responsibilities.
		§4.4.5 – Failure to meet ADOC procedure relocated to QA-WI002 section 5.
		§6.3.5 – New section addressing the control of new QA documents [CA #7345]
		§6.9 – Added flexible language to QA doc review procedure since revision history sections are now standard.
		§6.10.3 & 9.4.4.2 – Revised to meet the drinking water requirement for annual SOP reviews [CA #7346]
		§8.1 – Relocated all sample coordinating procedures to GEN-WI002.
		§8.2.5 – Added DW program work anticipated for 2016 and current audits being done by CRL analysts.
		§8.4.5 – Sample receiving procedures moved to GEN013 (sections 8.1.3, 8.1.7. 8.3.1, 8.3.3) if not already there.
		§9.4.4.4 – Included QC control charts to the annual SOP revision list of requirements.
		§9.6.8 – Revised the overarching LIMS qualifiers to include "Q" for QC limit exceeded. [CA#7468]
		§9.7.4 – Revised procedure for resolving data verification issues so that the CRL QA Coordinator is included when issues include QA/QC.
		§10.5.1.3 – Updated to reflect PT study participation for the upcoming drinking water certification.
		§13.7 – RL procedures relocated to QA-WI005 (now MDL & RL work instruction)
		Appendix 1 – Removed Praneeth Edirisinghe and Wendell Tomes from the staff listing; no longer employed at CRL
		§8.2.3 – ESAT work description elaborated to include allowable CRL practices in collaboration with ESAT.
		§8.4.4-8.4.5, 8.4.7, 8.5.6 – Procedures for sample handling including the disposal of spent bottles moved to SOP GEN013. Disposition of spent bottles for standards, reagents, and solvents were moved to SOP GEN026.
		§9.7.2 – data submittal and transmittal procedures moved to SOP GEN018.
		§10.5.1 – PT order determination procedure moved to QA-WI003 & added language to the subsection concerning repeated analyte failure to allow for not repeating analysis.
		§10.5.2 & 10.5.3 – Revised to more clearly describe external and internal audits at CRL. Internal audit procedures were moved to SOP GEN030.
		§10.7 – Revised to more clearly describe the nature of CAs at CRL. Moved monitoring and observation type of issues to section 10.5.3 and QC issues to section 13.4.
		§11 – Revised to include Qualtrax PA workflows and procedure moved to QA-WI019.
		§12.3.3.2 – Moved supporting equipment recertification schedule to SOP GEN026.
		§13.4 – Added a second paragraph to address consistent QC analyte failures.
		§13.5.5 – Revised section language to add flexibility.
		§13.5.7.1 – Elaborated on current ICV policy regarding meeting SOP limits.
For the description of modifications made to the CRL QMP versions #1-3, refer to the Revision History section of version #3.		